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Title 49
PUBLIC HEALTH—FOOD AND DRUGS
Part I. Regulations

Chapter 1. General Provisions

§101. Authority
[Formerly 49:1.0000]

A. These regulations are adopted under the authority of Act 142 of 1936 as amended by Act 185 of 1942.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§103. Mission
[Formerly 49:1.0010]

A. The primary mission of the Food and Drug Control Program is to protect consumers by assuring that products regulated by it are safe and perform as they are labeled or advertised. To achieve these objectives, the Unit engages in six general types of regulatory activities:

1. setting standards for product com position, manufacture, performance, and labeling;

2. evaluating, prior to marketing, the safety and effectiveness of those products that must have premarket clearance;

3. conducting inspections, surveys and analyses to monitor compliance with statutory requirements, administratively set standards, conditions of approval, etc.;

4. initiating enforcement action where necessary to effect compliance with the laws and implementing regulations;

5. informing and educating industry and consumers about the requirements of Louisiana Food and Drug laws and regulations; and

6. investigating corn plaints by Louisiana consumers concerning the alleged adulteration and/or misbranding of foods, drugs, cosmetics and medical devices in commerce.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§105. Scope
[Formerly 49:1.0020]

A. The provisions of regulations promulgated under the State Food, Drug and Cosmetic Act with respect to the doing of any Act shall be applicable also to the causing of such Act to be done.

B. The definitions and interpretation of terms contained in Section 602 of the Louisiana Food, Drug and Cosmetic Act shall be applicable also to such terms when used in regulations promulgated under that Act.

C. Any Louisiana citizen has a right to utilize the program's resources with respect to the following.

1. Request to see the files on any firm under inspection by the Food and Drug Control Program.

2. Obtain copies of any reports in the Food and Drug Control Program's files, except that proprietary information is not considered public information, e.g., a firm's product formula.

3. Address corn plaints to the Food and Drug Program about any product which is suspected of being defective in any way or which is suspected of having caused food poisoning or other injury.

4. Request information from the Food and Drug Program staff on products regulated by the Program. Proprietary information is the only information that cannot be divulged under this provision.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§107. Definitions
[Formerly 49:1.0030]

Act—Act 142 of 1936 as amended by Act 185 of 1942, unless the text clearly indicates a different meaning. All definitions and interpretations of terms given in the Act shall be applicable also to such terms when used in these regulations.

Analysis—includes examinations and tests.

Artificial Coloring—coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

Artificial Flavoring—a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

Chemical Preservative—any chemical which, when added to foods, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

Open Container—a container of rigid or semi-rigid construction, which is not closed by a lid, wrapper or otherwise (see Section 265).

Sell, Sale or Sold (wherever used in these regulations)—the sale; keeping, offering, or exposing for sale; having in possession for sale, delivery or distribution within the state of any product or article covered by the Act or these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§109. Cause of Act
[Formerly 49:1.0035]

A. Any regulation pertaining to the doing of any act shall also apply to the causing of such act to be done.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§111. Labeling Claims
[Formerly 49:1.0040]

A. The label or labeling of a product shall be deemed misleading if it makes a claim or statement concerning which there is a difference of opinion among experts, and fails to state that such a difference of opinion exists if there is a material weight of expert opinion contrary to the claim or statement.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§113. Guaranty
[Formerly 49:1.0050]

A. A guaranty or undertaking, referred to in Section 640 of the Act, shall be considered to have been given by each person signing such guaranty or undertaking.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§115. Guaranty for a Specified Shipment
[Formerly 49:1.0060]

A. A guaranty or undertaking limited to a specific shipment or other delivery of an article shall be a part of, or shall be attached to, the invoice or bill of sale covering such shipment or delivery.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§115. Limited Guaranty
[Formerly 49:1.0070]

A. The limited form of guaranty or undertaking shall state that the person giving the guaranty or undertaking guarantees that no article listed therein is adulterated or misbranded within the meaning of the State Food, Drug and Cosmetic Act (naming the Act), or that it is not an article which may not be introduced into commerce under the provisions of Section 640 of the Act and the guaranty shall bear the signature and post office address of the person giving the guaranty or undertaking.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§115. General or Continuing Guaranty
[Formerly 49:1.0080]

A. A guaranty or undertaking that is general or continuing in its application to any shipment or other delivery of an article, shall be considered as having been given at the date such article was shipped or delivered by the person giving the guaranty or undertaking.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§115. General Guaranty, Effective Date
[Formerly 49:1.0090]

A. The general, or continuing, form of guaranty or undertaking shall state that the article comprising such shipment or delivery made thereafter by the guarantor to, or on the order of, the person to whom the guaranty or undertaking is given (naming the person and giving his address) is guaranteed, as of the date of shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the State Food, Drug and Cosmetic Act (naming the Act); or is not an article which may not be introduced into commerce under the provisions of Section 640 of the Act, and shall bear the signature and post office address of the person giving the guaranty or undertaking.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§115. General Guaranty, Expiration
[Formerly 49:1.0100]

A. The application of a guaranty or undertaking, referred to in Section 640 of the Act to any shipment or other delivery of an article, shall expire when such article, after shipment or delivery of an article, shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking becomes adulterated or misbranded within the meaning of the Act, or becomes an

article which may not, under the provisions of Section 612 of said Act, be introduced into state commerce.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§117. General Guaranty, Signatures [Formerly 49:1.0110]

A. A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guaranty the article to which it applies.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§119. Use of the Term Labeling [Formerly 49:1.0120]

A. No representation or suggestion that an article is guaranteed under the State Food, Drug and Cosmetic Act shall be made in labeling.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§121. Hearings [Formerly 49:1.0130]

A. Hearings prescribed in Section 637 of the Act shall be private and informal.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§123. Hearing, Statements [Formerly 49:1.0140]

A. Statements presented at such hearings shall be confined to matters relevant to the contemplated proceeding. Such statements may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in Section 640 of the Act, the guaranty or undertaking referred to in Section 640 of the Act, the guaranty or undertaking, or a verified copy thereof, shall be submitted at the hearing.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§125. Hearing, Request for Change in time or Place [Formerly 49:1.0150]

A. The time or place, or both, appointed in the notice affording opportunity for a hearing under Section 637 of the Act, may be changed, upon request, reasonably made, addressed to the State Health Officer, by the person to whom the notice has been given, or by his representative, if the request states reasonable grounds therefor.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§127. Collection of Samples [Formerly 49:1.0160]

A. When any officer or employee of the department collects a sample of food, drug, cosmetic or device, for examination and investigation under the Act, the sample is collected from a shipment or other lot of the article which is displayed, offered for sale, held, stored or transported in intrastate commerce, or is in or was received in intrastate commerce. Only samples so designated by an officer or an employee of the department shall be considered to be official samples.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§129. Owner of the Lot [Formerly 49:1.0170]

A. The owner of a food, drug, or cosmetic, of which an official sample is collected, is the person who owns the shipment or other lot of the article from which the sample is collected.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§131. Size of Samples [Formerly 49:1.0180]

A. When an officer or employee of the department collects an official sample of a food, drug or cosmetic for analysis under the Act, he shall collect at least twice the quantity sufficient for analysis, unless:

1. the amount of the article available and reasonably accessible for sampling is less than twice the quantity so needed;

2. the cost of twice the quantity so needed exceeds $10;

3. the article is perishable; named on the label of the article, or his agent, and

4. the sample is collected from the owner of the article, or his agent, and such person is also the owner of the article;

5. the sample is collected from the owner of the article, or his agent, and such article bears no label, or, if it bears a label no person is named thereon; or

6. the analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§133. Collection for Trial Samples [Formerly 40:1.0190]

A. In addition to the quantity of sample prescribed above, the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as may be necessary for use as an exhibit in the trial of any case that may arise under the Act based on the sample.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§135. Reserved Samples [Formerly 49:1.0200]

A.1.Upon completion of analyses by the laboratory whereby it is established that any article subject to the provisions of the Act is adulterated, misbranded, or otherwise subject to the prohibitions of the Act, a sufficient amount of the sample (if any remains) shall be reserved as an exhibit in the trial of any case that may arise under the Act based on the sample. Upon written request, if any person named on the label of the article found adulterated, misbranded, or otherwise subject to the prohibitions of the Act, or owner thereof, or the attorney or agent of such person or owner shall be provided with a part of the sample for their analysis, if any remains, subject to the reservations above, except when:

a. the sample or remaining part thereof has, after collection become decomposed or otherwise fit for analysis; or

b. the request for a portion of the sample on which the trial action is based is not made within a reasonable time before the date the case is set for trial.

2. The person, owner, attorney, or agent, who requests the part of the ample, shall specify the amount desired. A request from an owner shall be accompanied by the evidence of ownership, and a request from an attorney or agent by evidence of authority from the4 person or owner to receive a part of the sample. When two or more requests for parts of the sample are receive4d, the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefore.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§137. Collection for Trial Samples [Formerly 49:1.0210]

A. When an official sample of a food, drug or cosmetic is the basis of a notice given under Section 637 of the Act, or of a case under the Act, and the person who is a party to the case, has a right under §135 to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request, provided the request is accompanied by a written waiver of right from the owner thereof and from each person named on the label of the article who has not exercised his right under §135. The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph §135.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§139. Collection for Trial Samples [Formerly 49:1.0220]

A. The head of the Food and Drug Division of the department is authorized to destroy or recommend for destruction:

1. any official sample when it has been determined that no analysis of the sample will be made:

2. any official sample, or part thereof, when it has been determined that no notice under Section 637 of the Act, and no case under the Act, is or will be based on the sample;

3. any official sample, or part thereof, when the sample was the basis of a notice under Section 637 of the Act, and when after opportunity for presentation of views following such notice, it has been determined that no other notice and no case under the Act, is or will be based on the sample:

4. any official sample or part there of when the sample was a basis of a case under the Act which has gone to final judgment; and when it has been determined that no other such case is or will be based on the sample;

5. any official sample or part thereof if the article is perishable;

6. any official sample or part thereof, when after collection such sample or part thereof has become decomposed or otherwise unfit for analysis;

7. that part of any official sample which is in excess of three times the quantity estimated by the laboratory as sufficient for analysis.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§141. Seizure
[Formerly 49:1.0230]

A. Any food, drug or cosmetic which is adulterated or misbranded within the provisions of the Act, and which has been manufactured for sale or is held in possession with intent to sell, offer or expose for sale, or is sold, transported or delivered for sale within this state, shall be liable to seizure as provided in R.S. 40: 633. Any product so seized shall be disposed of as follows.

1. Released under bond for reconditioning or relabeling in accordance with Section 632(c) of the Act, if after the analysis the product is found to be of such quality that it may be reconditioned or if the violation is one of misbranding that may be corrected by relabeling; provided that the reconditioning or relabeling; provided that the recondition or relabeling shall be done under the supervision of an officer or agent of the department.

2. Submitted to the court for a court order of condemnation and destruction in accordance with Section 634 of the Act, if after analysis the product is found to be adulterated but is not of a perishable nature or cannot be reconditioned and the owner refuses to authorize its destruction. If a judgment of condemnation and destruction is rendered against the product, the same shall be disposed of by destruction or sale as the court may direct, but such goods shall not be sold contrary to the provisions of the Food, Drugs and Cosmetic Act, or of these regulations.

3. Condemned and destroyed in accordance with Section 635 of the Act, if the material constitutes a nuisance as provided for in that section.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§143. Identification of Seized Goods
[Formerly 49:1.0240]

A. All goods placed under seizure shall be tabbed, marked or otherwise identified. The removal of such tags, marks or other identification by anyone other than an authorized officer or agent of the department is prohibited; and any such removal shall be considered prima facie evidence of intent to violate the law.

B. Such tags shall be removed only by the authorized officer or agent.

1. After analysis or examination has shown the goods to be not in violation of the law or these regulations; or

2. in accordance with an order of any court or competent jurisdiction; or

3. after the goods have been reconditioned or relabeled under bond and are no longer in violation of the Act.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

Chapter 2. Food Regulations

§201. Misbranding
[Formerly 49:2.0000]

A. A food shall be deemed misbranded:

1. if any representation in the labeling is false or misleading with respect to another food;

2. if the food contains two or more ingredients and the designation of the food in the labeling is by a name which includes or suggests the name of one or more but not all ingredients even though the names of all ingredients are stated elsewhere in the labeling.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§203. Label, Firm Name
[Formerly 49:2.0010]

A. Where the name which appears on the label of any food is not that of the manufacturer, the name shall be qualified by a phrase which reveals the connection such person has with the food, such as "Manufactured for and Packed by _", "Packed for _", "Distributed by", or other similar phrase which expresses the facts; Provided, the name of the actual manufacturer or packer shall be furnished to the department upon request.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§205. Label, Principal Place of Business
[Formerly 49:2.0020]

A. Where a person manufactures, packs, sells, or distributes a food at a place other than his principal place of business, the label may state the principal place of business instead of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§207. Label, Cannot Be Misleading [Formerly 49:2.0030]

A. The requirement that the label shall contain the name and place of business of the manufacturer, packer, seller, or distributor, shall not be considered to modify any requirement that the label shall not be misleading in any particular.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§209. Quantity of Contents [Formerly 49:2.0040]

A. The statement of the quantity of the contents shall reveal the quantity of food in the packages, exclusive of wrappers and other material packed with such food.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§211. Statement of Quantity of Contents [Formerly 49:2.0050]

A. The statement of the quantity of the contents shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. If no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semi-solid, viscous, or a mixture of solid and liquid.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§213. U.S. Measure Quantity of Contents [Formerly 49:2.0060]

A. A statement of the quantity of the contents by weight shall be in terms of the avoirdupois pound and ounce. A statement of the quantity of the contents by liquid measure shall be in terms of the United States gallon of 231 cubic inches and of the quart, pint and fluid ounce sub-divisions thereof, and, except in case of frozen food which is offered for sale as such, shall express the volume at 68 degrees Fahrenheit (20 degrees Centigrade). A statement of the quantity of the contents by dry measure shall be in terms of the United States bushel of 2150.43 cubic inches and of the peck, dry quart and dry pint subdivisions thereof; or in terms of the United States standard barrel and it subdivisions of third, half and three quarters barrel. However, in the case of export shipment, the statement may be in terms of system of weight or measure in common use in the country to which such shipment is exported.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§215. Metric Labeling Quality of Contents [Formerly 49:2.0070]

A. A statement of weight or measure in the terms specified in §213 may be supplemented by a statement in terms of the metric systems of weight or measure.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§217. Numerical Count Quantity of Contents [Formerly 49:2.0080]

A. Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by a statement of weight, measure, or size of the individual units of the food such as will give accurate information.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§219. Use of Fractions—Quantity of Contents [Formerly 49:2.0090]

A. Statements of quantity of contents shall contain only those fractions that are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms: a decimal fraction shall not be carried out to more than two places.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§221. Largest Whole Units—Quantity of Contents [Formerly 49:2.0100]

A. If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in §213 and which is applicable to the food under the provisions of §209 and §211 the statement shall express, (except as provided in §223) the number of the largest of such units contained in the package; for example, the statement on the label of a package which contains one quart of food shall be "1 quart", and not "2 pints" or "32 fluid ounces."

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§223. Fractions of Whole Units—Quantity of Contents [Formerly 49:2.0110]

A. Where a number is a whole and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in §225; for example, 1-3/4 quarts may be expressed as "1 quart 1-1/2 pints" or "1 quart 1 pint 8 fluid ounces"; 1-1/4 pounds may be expressed as "1 pound 4 ounces."

B. The stated number of any unit which is smaller than the largest unit, (specified in §213) contained in the package, shall not equal or exceed the number of such smaller units in the next larger unit so specified; for example, instead of "1 quart 16 fluid ounces", the statement shall be "1-1/2quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1-1/2 pounds" or "1 pound 8 ounces".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§225. Unit Designations—Quantity of Contents [Formerly 49:2.0120]

A. In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be in accordance with such custom if it is informative to consumers; for example, instead of "1 pint 9 fluid ounces" spiritous liquors may be labeled "4/5 quart" or "1/5 gallon."

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§227. Minimum or Average Quantity—Quantity of Contents [Formerly 49:2.0130]

A. The statement of the quantity of contents of the package shall express the minimum or the average quantity. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to mean the average quantity.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§229. Minimum Quantity Stated—Quantity of Contents [Formerly 49:2.0140]

A. Where the statement expresses the minimum quantity no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is received from interstate commerce or introduced into state commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§231. Variations Permitted—Quantity of Contents [Formerly 49:2.0150]

A. Where the statement does not express the minimum quantity variations shall be permitted:

1. when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

2. when caused by unavoidable deviations in weighing, measuring or counting individual packages which occur in good packing practice. But variations shall not be permitted to such an extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though averages in other packages in the same shipment of delivery compensate for such shortage.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§233. Determining Permitted Variations—Quantity of Contents [Formerly 49:2.0160]

A. The extent of variations from the stated quantity of the contents permissible under §229 and §231 shall be determined by the facts in the case of each individual shipment or other delivery.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§235. Label Exemptions from Misbranding Provisions [Formerly 49:2.0170]

A. Labels of food packages shall be exempt from compliance with the requirements of Section 608, (5), (b) of the Act if:

1. the quantity of the contents, as expressed in terms applicable to the food under the provisions of §213 is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or if there are less than six units in case the units of the food can be easily counted without opening the package;

2. the container is so small that the statement of the quantity of the contents of the package, together with all

other words, statements and information required by or under authority of the Act to appear on the label, cannot, because of insufficient area for larger label space, be placed on the label so as to comply with the requirements of Section 608 (c) of the Act and regulations promulgated thereunder.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§237. Misbranding—Labels Lacking Prominence or Conspicuousness [Formerly 49:2.0180]

A. A word, statement or other information required by or under authority of the Act to appear on the label shall be deemed to lack that prominence and conspicuousness required by Section 608 (6) of the Act by reason (among other reasons) of:

1. the failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; or

2. the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be under customary conditions of purchase, the part of panel displayed; or

3. the failure of the label to extend over the area of the container or package available for extension of the label so as to provide sufficient label space for the prominent placing of such word, statement of information; or

4. insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space for any word statement, design, or device which is not required by or under authority of the Act to appear on the label; or

5. insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information or to any design or device; or

6. smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written printed or graphic matter.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§239. Misbranding—Misuse of Label Space [Formerly 49:2.0190]

A. No exemption depending on insufficiency of label space as prescribed in §237 and §253 promulgated under Section 608 (5) or (9) of the Act, shall apply if such insufficiency is caused by:

1. the use of label space for any word, statement, design or device which is not required by or under authority of the Act to appear on the labeling; or

2. the use of label space to give greater conspicuousness to any word, statement, or other information that is required by Section 608 (6) of the Act: or

3. the use of label space for any representation in a foreign language.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§241. Misbranding—Use of the English Language Required [Formerly 49:2.0200]

A. All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§243. Misbranding—Use of a Foreign Language [Formerly 49:2.0210]

A. If in addition to the required information the label or labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the foreign language.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§245. Misbranding—Ingredient Name [Formerly 49:2.0220]

A. The name of an ingredient (except a spice, flavoring or coloring) required by Section 608 (9) (b) of the Act to be borne on the label of a food, shall be a specific name and not a collective name. However, if a compound ingredient (which itself contains two or more components) conforms to a definition and standard of identity prescribed for such a compound by regulations under R.S. 40:610, such a compound may be designated on the label of the food by the names specified in the definition and standard, supplemented in case the regulations require the naming of optional components present in such a compound ingredient, by a statement showing the optional components which are present in the compound ingredient.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§247. Misbranding—Spice, Flavoring or Coloring Misbranding [Formerly 49:2.0230]

A. No ingredient shall be designated on the label as a spice flavoring or coloring, unless it is a spice, flavoring or coloring, as understood by consumers. The term "coloring" shall not include any bleaching substance.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§249. Misbranding—Ingredient has More than One Use [Formerly 49:2.0240]

A. An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such an ingredient is designated by its specific name.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§251. Misbranding—Misleading Labels [Formerly 49:2.0250]

A. A label may be misleading by reason (among other reasons) if:

1. the order in which the name of ingredients appear thereon, or the relative prominence otherwise given such names; or

2. its failure to reveal the proportion of, other fact with respect to, an ingredient, when such a proportion or other fact is material in the light of representation that the ingredient was used in fabricating the food.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§253. Misbranding—Assorted Foods [Formerly 49:2.0260]

A. Labels of food packages shall be exempt from compliance with the requirements of Section 608 (9) (b) of the Act if the container is so small that the label when extended over the area available for label space is of insufficient size so that all words, statements and other information required by or under authority of the Act to appear on the label cannot be so placed on the label as to comply with the requirements of Section 608 (6) of the Act and §215 with its subparagraphs. This exemption shall be on the condition that if the statement of the quantity of contents is omitted as authorized by §235.A. 2 under Section 608 (5) of the Act, and this omission will allow sufficient space to include the information required by Section 608 (9) (b) even though the statement is not so conspicuous as to be likely to be read by the ordinary individual under customary conditions of purchase then the statement of the quantity of contents shall be omitted and the information required by Section 608 (9) (b) of the Act shall be stated as prominently as is practicable.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§255. Misbranding—Variation in Ingredients [Formerly 49:2.0270]

A. When an assortment of different foods are packed together and there are variations in the kinds and amounts of these different foods within the various individual packages resulting in variations in the ingredients in the different packages such as would occur normally in good packing practice, the requirements of Section 608 (9) (b) of the Act with respect to any ingredient which is not common to all packages need not be com plied with. However, such exemption shall be on the condition that the label shall bear a statement indicating in terms as informative as practicable, and not misleading, that other ingredients may be present.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§257. Chemical Preservatives [Formerly 49:2.0280]

A. The use of any chemical preservative in or on any food or food product is prohibited, except as hereinafter provided:

1. sodium benzoate shall be permitted to be used in foods or food products as a preservative, in amounts not to exceed 1/10 of 1 percent of the weight of the food or of the volume of the food in case of fluids; provided the food or food product is properly labeled to show the presence and amount of sodium benzoate; and provided, further, that such food or food product cannot be satisfactorily kept from spoilage under good sanitary methods without the addition of sodium benzoate within the above-prescribed amount; and provided, further, that no definition or standard of identity has been promulgated wherein chemical preservatives are specifically prohibited for such food or food product.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§259. Misbranding—Food not in Package Form [Formerly 49:2.0290]

A. A food subject to the requirements of Section 608(11) of the Act shall be labeled according to those requirements,

except as provided in §263, even though the food is not in package form.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§261. Misbranding—Artificial Flavoring, Coloring or Preservative
[Formerly 49:2.0300]

A. A statement of the presence of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the label of the food, or on its container or wrapper; or on any two or all of these, as may be necessary to render the statement likely to be read by an ordinary individual under customary conditions of purchase and use of the food.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§263. Misbranding Exemption—Package Size
[Formerly 49:2.0310]

A. A food shall be exempt from compliance with the label requirements of Section 608 (11) of the Act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on the units with such prominence as to render it likely to be read by an ordinary individual under customary conditions of purchase and use.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§265. Misbranding—Open Containers
[Formerly 49:2.0320]

A. An open container of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of R.S. 40:608(5) and (7)(b) (with respect to the name of the food specified in the definition and standard), and, of Section 608 (9) (a) of the Act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, the crate or package shall bear labeling showing the number of containers enclosed therein and the quantity of the contents of each.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§267. Misbranding—Food to be Labeled, Processed or Packed
[Formerly 49:2.0330]

A. A food which is to be labeled, processed or repacked in substantial quantities in accordance with regular trade practice, at an establishment other than that where originally processed or packed, shall be exempt, except as provided by §269 and §271, from compliance with the labeling requirements of Section 608 (3), (7), (8), (9), (10), (11) of the Act during transit from the original establishment to the labeling, processing or repacking plant, if:

1. the person responsible for the transit of the food in commerce is the operator of the establishment where the food is to be labeled, processed, or repacked; or

2. the shipment or delivery of food is made under a written agreement, signed by and containing the post office addresses of the person responsible for the shipment or delivery and the operator of the labeling, processing, or repacking plant and also containing specifications for the labeling, processing, or repacking, as the case may be, which if followed will ensure that the food will not be adulterated or misbranded within the meaning of the Act upon completion of the labeling, processing, or repacking. Each party to the agreement shall keep a copy of the agreement until all the food or foods subject to its terms have been removed from the labeling, processing or repacking establishment and copies of the agreement shall be made available at any reasonable hour for inspection by any officer or employee of the Board who requests them.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§269. Misbranding—Exemption Void
[Formerly 49:2.0340]

A. Any exemption of a food under §267(A)(1) shall immediately be void if the food, or any part thereof, at time of removal from the original establishment is adulterated or misbranded within the meaning of the Act when so removed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§271. Misbranding—Agreement
[Formerly 49:2.0350]

A. An exemption of a food under §267(A)(2) shall immediately become void:

1. upon refusal by the person responsible for the shipment or delivery of the food to make available for inspection a copy of the agreement specified in, and required by §267(A)(2);

2. upon refusal by the operator of the establishment where the food is to be labeled, processed, or repacked to make available for inspection a copy of the agreement specified in, and required by §267(A)(2);

3. if the food, or any part thereof, at time of removal from the original establishment is adulterated or misbranded within the meaning of the Act when so removed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§273. Misbranding—Dyes and Colors [Formerly 49:2.0360]

A. Only harmless animal or vegetable dyes and such coal-tar colors as have been certified by the Federal Food and Drug Administration under authority of Federal Food, Drug and Cosmetic Act of 1938 and defined under coal-tar color regulations as published in Federal Security Agency, Service and Regulatory Announcements FDC 3, issued September, 1940, or as amended from time to time, shall be used in, offered for sale for use in, or distributed for use in or on foods, or their containers where the container is of a style or type so that the color or dye may come in direct contact with the contained food.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

Chapter 3. Bottled Water Labeling Regulations

§301. Definitions [Formerly 49:2.1100]

Package—any container in which any bottled water is enclosed for use in the delivery or display of such commodity to retail purchasers, but does not include:

1. shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors or wholesalers or retail distributors;

2. shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity;

3. five gallon containers of water intended for use in water vending machines, water coolers or dispensers.

Principal Display Panel (as it applies to water in package form and as used in this part)—the part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale.

Bottled Water—water that is sealed in bottles or other containers and intended for human consumption. Bottled water includes spring water, artesian water, purified water and drinking water, but does not include mineral water, sparkling water or any soda water products.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 11:102 (February 1985).

§303. Labeling Outer Container or Wrapper [Formerly 49:2.1110]

A. A requirement contained in this part that any word, statement or other information which appears on the label shall not be considered to be complied with unless such word, statement or information also appears on the outer container or wrapper of the retail package.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§305. Identity Labeling of Water in Packaged Form [Formerly 49:2.1120]

A. The principal display panel of a water in packaged form shall bear as one of its principal features a statement of the identity of the commodity.

B. Such statement of identity shall be in terms of:

1. the common or usual name of the water, indicating the source of the water, or in the absence thereof;

2. an appropriately descriptive name indicating the source of the water;

3. this statement of identity shall be in terms of:

a. this statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§307. Water, Designation of Additives [Formerly 49:2.1130]

A. The chemical name and concentrations of any preservatives or additives added to a bottled water shall be declared on the principal display panel immediately below the identity statement in type size not less than 6.0 points. Preservatives or additives added to bottled water shall be listed by common or usual name in descending order of predominance by weight.

B. The name of a preservative or additive shall be a specific name and not a collective (generic) name.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§309. Water; Designation or Treatment Methods [Formerly 49:2.1140]

A. The principal display panel of water in packaged form shall bear as one of its principal features a statement of the method of treatment to which it has been subjected. The treatment shall be identified by its common or usual name, e.g., activated carbon filtration, etc.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§311. Water; Labeling of Five Gallon Containers [Formerly 49:2.1150]

A. The labeling requirements for water packaged in five gallon containers or larger, intended for use in water coolers, water vending machines or dispensers, will be deemed complied with if all mandatory labeling information required by this part appears on the cap or crown.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

Chapter 4. Water Vending Machines Regulations

§401. Definitions [Formerly 49:2.1200]

Water Vending Machine—any self—service device which, upon insertion of money or tokens or upon receipt of payment by other means, dispenses unit servings of water in bulk into a container, without the necessity of refilling the machine between each operation.

Permit—shall mean and be limited to a permit issued under and pursuant to the provisions of these regulations.

Vended Water—that water dispensed by means of a water vending machine.

Person—any individual, public or private corporation, company, association, partnership, municipality or any other legal entity or its legal representative, agent or assigns.

Operator—any person who owns or operates a water vending machine.

Potable Water—water which meets the requirements of Chapter VIII of the Louisiana State Sanitary Code of January 1, 1977 and any subsequent revisions.

Spring Water—water obtained from a water source which flows naturally from an underground spring or is obtained from such spring by means of drilling and/or pumps.

United States Pharmacopeia—the "Pharmacopeia of the United States of America prepared under authority of the United States Pharmacopeial Convention"; a book of standards for drugs, tests, waters and reagents.

Purified Water—water produced by distillation, deionization, reverse osmosis or other methods as defined in the current edition of the "United States Pharmacopeia".

Non-Toxic Materials—materials which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor or microbiological quality of the water.

Approved—approved in writing by the designated representative of the State Health Officer.

Sanitary—promoting or pertaining to health and, therefore, free of harmful or deleterious contaminants.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 10:10 (January 1984).

§403. Operating Requirements [Formerly 49:2.1210]

A. Each water vending machine operator shall:

1. obtain a permit for each water vending machine operated;

2. install each water vending machine to a potable water supply in accordance with the State Sanitary Code and any applicable, local plumbing codes;

3. operate and maintain all water vending machines in a sanitary manner;

4. maintain adequate water quality monitoring by analyzing one sample every three months bacteriologically from each water vending machine;

5. take investigative or corrective action, in cooperation with the Food and Drug Control Unit, as necessary when a vending machine malfunctions to assure that a pure, wholesome and potable water supply is supplied to consumers.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 10:10 (January 1984).

§405. Permits [Formerly 49:2.1220]

A. Each person desiring to operate a water vending machine in Louisiana shall, prior to such operation, apply to the State Health Officer for a perm it.

B. Any application for a permit shall be on a form as prescribed by the State Health Officer and shall contain the following:

1. name and principal address of the applicant;

2. address of the proposed water vending machine location. A separate application for permit must be filed for each water vending machine location.

3. signature of a responsible officer of the firm and his/her title;

4. any additional information needed for the orderly maintenance of records and data processing requirements;

5. the model number or name of the water vending machine;

6. evidence with respect to each model of machine intended to be used, that:

a. said model com plies with the construction standards of the National Sanitation Foundation (NSF) and/or the National Automated Merchandising Association (NAM A). Such standards are available from the National Sanitation Foundation, 3475 Plymouth Rd., Ann Arbor, Michigan 48105 and/or the National Automated Merchandising Association, 7 S. Dearborn St. Chicago, Illinois 60603;

b. all exterior and interior surfaces and component parts of said machine are designed and constructed to permit easy cleaning and maintenance;

c. all parts and surfaces of said machine with which the water comes into contact are non-toxic, corrosion resistant, non-absorbent material capable of withstanding repeated cleaning and sanitizing treatment.

d. said machine has a recessed or guarded corrosion resistant dispensing spout;

e. all treatment of the vended water by distillation, ion-exchange filtration, ultraviolet light, reverse osmosis, mineral addition or any other process is done in a manner so as to accomplish its intended purpose of purifying water;

f. all vending machines are located in an area that can be maintained in clean condition and in a manner that avoids insect and rodent harborage.

g. the source of water supply is from a community water supply approved by the State Health Officer as defined in the State Sanitary Code, Sect. 8.1;

h. all machines have a system of collection and handling of drip, spillage and overflow of water;

i. all connections with the public water supply have a backflow prevention device approved by the State Health Officer;

j. all vending machines display, in a position clearly visible to customers, the following information: the name, license number and address of the operator, the fact that the water is obtained from a public water supply, a statement describing the treatment process; if no treatment process is utilized, then a statement to that fact, chemical names and concentrations of any preservatives or additives and a local telephone number than may be called for further information, service or complaints;

k. prior to delivery into the customer's container, water vended by the machine is disinfected by ultraviolet light or other method approved by the Health Officer;

l. all water vending machines are equipped with monitoring devices designed to shut down operation of the machine when the disinfection unit fails to function;

m. all vending machines are equipped with a self-closing, tight-fitting door on the vending compartment;

n. no vended water is described on a machine or elsewhere as "spring water" or "purified water" unless such water conforms to the definition contained in this Part.

o. activated carbon, if used, complies with the American Water Works Association (A WWA) specifications for granular, activated carbon used in the treatment of potable water (A WWA B 604-74);

p. all vending machines are maintained in a clean and sanitary condition, free from dirt and vermin.

C. Evidence that the person applying for permit has:

1. a competent and responsible staff approved by the State Health Officer for the local supervision of the operation of the machines. Competent staff shall be construed to mean a person or persons with at least one year's experience concerning the proper operation of the type of water vending machine they will operate. (Or similar training or experience in this or related operations);

2. an acceptable maintenance program for the routine servicing of water vending machines. The program shall include written servicing instructions for the operator, technical manuals of the machine and of the water treatment appurtences involved and regularly scheduled service visits;

D. Issuance of Permit. The state health officer, after a reasonable period of time, shall either grant or deny an applicant a permit.

E. Permit revocation and cancellation. Each permit issued in accordance with the provisions of this Part, shall be for a period of one year and shall remain if force and effect for that period unless terminated, revoked or cancelled upon due notice and hearing.

F. Fees. Each person applying for a permit to operate a water vending machine within Louisiana shall pay an initial and an annual permit fee of $100 (Reference LSA R.S. 40:701.1, Act No. 125 of 2000).

G. Each water vending machine permitted for use in Louisiana shall display, in the upper right hand corner of the front panel, a permit decal furnished by the State Health Officer.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 10:10 (January 1984).

§407. Service, Sampling and Records [Formerly 49:2.1230]

A. All parts and surfaces of the water vending machines shall be maintained in clean condition by the water vending operator. The vending chamber and vending nozzle of each machine shall be cleaned and sanitized each time the machine is serviced. A record of cleaning and maintenance operations shall be kept by the operator for each water vending machine.

B. The vended water from each water vending machine shall be analyzed once every three months for total coliforms. The analysis shall be performed by a laboratory approved by the State Health Officer in accordance with the provisions of the EPA Manual #600/8-78-008 titled "Manual for the Interim Certification of Laboratories Involved in Analyzing Public Water Supplies Criteria and Procedures, May, 1978". This manual is prepared by the United States EPA, 1201 Elm St., Dallas, Texas 75270.

C. The vended water from each water vending machine utilizing silver—impregnated carbon filters in the treatment process shall be analyzed once every three months for silver. The analysis shall be performed by a laboratory approved by the State Health Officer in accordance with the provisions of the EPA Manual #600/8-78-008 titled "Manual for the Interim Certification of Laboratories Involved in Analyzing Public Water Supplies Criteria and Procedures, May, 1978".

D. A more frequent analysis of the above parameters, or additional analysis may be required by the State Health Officer if there is some presumption of unfitness of the vended water because of the presence of undesirable elements, compounds or materials caused by the passage of water through the machine.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 10:10 (January 1984).

Chapter 5. Registration of Foods, Drugs, Cosmetics and Prophylactic Devices

§501. Definitions [Formerly 49:2.2100]

A. Unless otherwise specifically provided herein, the following words and terms used in this Chapter of Title 49, and all other Chapters of Title 49 which are adopted or may be adopted, are defined for the purposes thereof as follows.

Accrediting Body—for the purposes of this Chapter, the International Organization for Standardization (ISO).

Adult-Use Consumable Hemp Product—any consumable hemp product that contains more than 0.5 milligrams of THC per package.

Advertisement—includes all representations of fact or opinion disseminated to the public in any manner or by any means other than by the labeling.

Certificate of Analysis—a document produced by an approved laboratory attesting to the composition of a product.

Certificate of Consumable Hemp Product Registration (FD-8a)—certificate issued by the department attesting that consumable hemp products produced or distributed by the holder's company have been registered as required.

Certificate of Registration (FD-8)—certificate issued by the department attesting that products produced or distributed by the holder's company have been registered as required.

Consumable Hemp Product—any product derived from industrial hemp that contains any naturally-occurring cannabinoid, including cannabidiol, and in intended for consumption or topical use. This special class of products includes, but is not limited to, the following: food, animal foods or feed, hemp flower, and pet products. No consumable hemp product may contain a total THC concentration in excess of one percent on a dry-weight basis.

Consumable Hemp Products Database—repository of information on products and firms that are registered with the Food and Drug/Milk and Dairy Unit of LDH/OPH that fall into the category of consumable hemp products.

Cosmetic—includes all substances and preparations intended for cleaning, altering the appearance of or promoting the attractiveness of a person. The term includes soaps only when medicinal or curative qualities are claimed by the use, thereof.

Department—for the purposes of this Chapter, the Food and Drug/Milk and Dairy Unit of the Office of Public Health, Louisiana Department of Health.

Device—includes all devices intended for use in diagnosis, treatment, cure or prevention of disease in man or beast or intended to affect the structure of any function of the body.

Dietary Supplement—a product other than tobacco intended to supplement the diet that is not represented for use as a conventional food, that is not a drug, and that is labeled as a dietary supplement and bears or contains one or more of the following dietary ingredients or a concentrate, metabolite, constituent, extract, or combination thereof: a vitamin, a mineral, a botanical, an amino acid, or a dietary substance for use by man to supplement the diet by increasing the total dietary intake.

Drug—includes all substances and preparations recognized in the official compendium as defined in the State Food, Drug and Cosmetic Law. It includes all substances and preparations intended for use in the

diagnosis, treatment, cure or prevention of disease in man or beast, and all substances and preparations other than food and cosmetics, intended to affect the structure or any function of the body.

Examination and Investigation Fee—as required by R.S. 40:628, shall be referred to as registration fee.

Federally Defined THC Level for Hemp—the greater of the following:

a. A delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.

b. The THC concentration for hemp defined in 7 U.S.C. 1639o.

Food—includes all substances and preparations used for or entering into the composition of food, drink, confectionery, chewing gum or condiment for man or beast.

Industrial Hemp—the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.

Industrial Hemp-Derived Cannabidiol Products (IHDCP)—any industrial-hemp derived product that contains CBD intended for consumption or topical use.

Industrial Hemp-Derived Cannabidiol Products Database—repository of information on products and firms that are registered with the department that fall into the category of industrial hemp-derived cannabidiol products.

Label—the principal display or display of written, printed or graphic matter upon any food, drug, cosmetic or device or the immediate container, thereof, or upon the outside container or wrapper, if any, of the retail package of any food, drug, cosmetic or device.

Labeling—includes all labels and other written, printed and graphic matter in any form whatsoever accompanying any food, drug, cosmetic or device.

Medical Opinion—the opinion, within their respective fields, of the practitioners of any branch of the medical profession, the practice of which is licensed by law in this State.

Package—container or wrapping in which any consumer commodity is enclosed for the purposes of display or delivery to retail purchasers.

Patent or Proprietary Medicine—any drug or drug product covered by a patent from the U.S. Patent Office in Washington, D.C. and/or products sold under proprietary marks or trademarks with a distinctive device or brand to designate the source of origin.

QR Code—quick response code, a type of machine-readable, two-dimensional barcode that stores information about a product.

Registration Fee—examination and investigation fee.

Safe—that a product under the conditions of its intended use is not dangerous to the health of man or animal.

Scientific Opinion—the opinion, within their respective fields, of competent pharmacologists, physiologists or toxicologists [R.S. 40:602(12)].

Serving—total quantity of discrete units or of liquid in a package a processor recommends for consumption at one time.

THC—a combination of tetrahydrocannabinol and tetrahydrocannabinolic acid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020), LR 47:479 (April 2021), LR 48:1290 (May 2022), repromulgated LR 48:1583 (June 2022), amended LR 48:2982 (December 2022).

§503. Registration Provisions [Formerly 49:2.2110]

A. In accordance with the provisions of R.S. 40:627, each manufacturer, packer or proprietor of processed foods, drugs, proprietary or patent medicines, prophylactic devices and cosmetics in packaged form shall register each separate and distinct product annually with the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020), LR 47:479 (April 2021).

§505. Notice of Renewal, Application for Registration, Firm Name [Formerly 49:2.2120]

A. Each firm which is required to register products shall be notified at least 30 days in advance of the expiration date for the current certificate of registration. Notification shall be made in letter form and shall include the appropriate application for registration. Application for registration must be made in the name of the firm appearing on the labels.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§507. Safety and Efficacy [Formerly 49:2.2130]

A. Products containing new ingredients cannot be registered unless the application for registration is supported by full reports of investigations which have been made to show whether or not such product is safe for use and, if a drug or device, is effective in use. Such information will not be required; however, if the product has been approved by the U.S. Food and Drug Administration and the application for registration is supported by a copy of that approval.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§509. Product Registration Procedure [Formerly 49:2.2140]

A. In accordance with the provisions of R.S. 40:627 and 628 and in order to establish revised procedures for the annual registration of products, manufacturers, packers, processors and distributors of all processed foods, drugs, proprietary or patent medicines, prophylactic devices and cosmetics in packaged form, whose names appear on the labels, must submit an application for registration of such products on or before July 1 of each year. Certificates of registration will be issued to each firm for a period of one year expiring on June 30 of each year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, LR 10:9 (January 1984), LR 9:562 (August 1983), amended by the Department of Health and Human Resources, Office of Preventive and Public Health Services LR 11:1161 (December 1985), amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020), LR 47:479 (April 2021).

§515. Penalty Fee Assessment [Formerly 49:2.2170]

A. The late registration penalty fees as established by Act 344 of the 1985 Louisiana Legislature will assess each manufacturer, packer, or proprietor a penalty of $10 for failure to register each separate and distinct product annually. The penalty assessed shall be in addition to the examination and investigation charge (registration fee). No manufacturer, packer, or proprietor shall be assessed a late registration penalty fee of more than $100 in any calendar year.

B. Late penalty fees shall be assessed as follows:

Number of Products Registered	Penalty Fee
1	$ 10
2	$ 20
3	$ 30
4	$ 40
5	$ 50
6	$ 60
7	$ 70
8	$ 80
9	$ 90
10	$100
More than 10	$100

C. Late registration penalty fees will be imposed on those firms which fail to submit an application for registration and registration fees on or before July 1 of each year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:604 and R.S. 40:627(D).

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, LR 10:9 (January 1984), LR 9:562 (August 1983), amended by the Department of Health and Human Resources, Office of Preventive and Public Health Services LR 11:1161 (December 1985), amended by the Department of Health, Office of Public Health, LR 46:359 (March 2020).

§517. Registration of Consumable Hemp Products

A. In accordance with the provisions of R.S. 3:1482 as promulgated by the 2021 legislature, manufacturers or distributors of consumable hemp products must register each separate and distinct product with the department-annually and initially within 90 days of the effective date of these regulations or prior to marketing the products in the state of Louisiana, whichever comes first.

B. The manufacturer of any product that is not registered within the specified timeframe will be deemed to be in violation of these rules with respect to such product(s).

C. In lieu of the annual examination and administration charge normally collected under R.S. 40:628(B), the applicant for a consumable hemp product registration must provide (both initially and on or before July 1 of each year) the department with an application form, a cashier's check or money order made payable to the department in the amount of $50 per each separate and distinct product, specimen copies of labeling in paper or electronic format, laboratory accreditation verification documentation, a copy of the current grower or processor's license issued by the authority of competent jurisdiction for the firm responsible for hemp crop from which the products are derived, and a list of all products the applicant wishes to register with the department. If the packet meets these regulatory requirements, the department will issue to the applicant an FD-8a certificate of consumable hemp product registration and the application information will be entered into the consumable hemp products database.

D. No person is authorized to distribute any consumable hemp products in the state of Louisiana unless that person has first obtained a certificate of consumable hemp product registration from the department, except that if a firm submits product labeling and supporting documentation for review to the department and does not receive a response in writing within 15 business days of that initial submission, the product may be sold after the fifteenth business day by any permitted wholesaler or retailer until the submitting party receives notice in writing from the department that the product in question is accepted or rejected for registration.

E. Any firm may apply with the department for the designation of its products as "Louisiana hemp products," provided that those products are produced from hemp grown in Louisiana and are processed at a Louisiana-based manufacturer. These items will be designated with a special mark on the department's list of registered products once they have been registered with the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483(L) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:479 (April 2021), LR 48:1290 (May 2022), amended LR 48:2982 (December 2022).

§519. Consumable Hemp Products Labeling Requirements: Certificate of Analysis

A. Consumable hemp products must bear labeling that includes a scannable bar code, QR code, or a web address linked to a document or website containing the certificate of analysis for that product.

B. The certificate of analysis must be from a laboratory that is accredited by the Louisiana Department of Health, Office of Public Health (LDH/OPH). Accreditation will be demonstrated by the availability of a current audit from a third-party entity indicating that the laboratory meets the criteria specified in Standard 17025 of the accrediting body.

C. The certificate of analysis must include, at a minimum, the following information:

1. the batch number of the product;

2. the date the batch was received by the laboratory;

3. the date the testing was completed;

4. the laboratory methodology used for each analysis referenced in the report;

5. a cannabinoid profile listing all major phytocannabinoid constituents by percentage of dry weight;

6. serving size for the product, total THC (as defined in R.S. 3:1481) per serving, number of servings per package, and total THC per package (expressed in terms of milligrams per gram);

7. the amount of any detected residual solvent in the product in the product in parts per million, except that this analyte will not be required for floral hemp material; detections may not meet or exceed the following amounts:

a. butanes—800 ppm;

b. heptanes—500 ppm;

c. benzene—1 ppm;

d. toluene—1 ppm;

e. hexanes—10 ppm;

f. xylenes—1 ppm;

g. ethanol—5,000 ppm;

8. the amount of any detected pesticide residues in the product in parts per million; any detection above the limit of quantitation for a category I pesticide (see Table 1 of this Section) is defined as an exceedance and a basis for rejection of the product by the department; category II pesticides have maximum contaminant levels as defined in Table 1;

9. the amount of any microbiological contaminants in the product in appropriate units; total yeast/mold may not meet or exceed 10,000 colony-forming units per gram and total pathogenic *Escherichia coli* bacteria or *Salmonella* spp. may not meet or exceed 1 colony-forming unit per gram;

10. the amount of any detected heavy metal traces in the product in parts per million; detections may not meet or exceed the following amounts:

a. arsenic (As)—10 ppm;

b. cadmium (Cd)—4.1 ppm;

c. lead (Pb)—10 ppm;

d. mercury (Hg)—2 ppm.

D. No consumable hemp product may contain more than 0.3 percent delta-9 THC or one percent total THC on a dry-weight basis. Except for floral hemp material, no consumable hemp product may contain more than eight milligrams of total THC per serving. Products registered prior to the effective date of this rule exceeding the per-serving threshold may be sold until January 1, 2023.

E. Table 1: Category I and II Pesticides

Name	Maximum Contaminant Level (MCL) in ppm
Category I (includes aldicarb, carbofuran, chlorpyrifos, coumaphos, daminozide, dichloryos, dimethoate, ethoprop(hos), etofenprox, fenoxycarb, imazalil, methocarb, methyl parathion, meyinphos, paclobutrazol, propoxur, spiroxamine, and thiacloprid)	0
Category II	
Abamectin	0.3
Acephate	5
Acetamiprid	5
Acequinocyl	4
Azoxystrobin	40
Bifenazate	5
Bifenthrin	0.5
Boscalid	10
Captan	5
Carbaryl	0.5
Chlorantraniliprole	40
Clofentezine	0.5
Cyfluthrin	1
Cypermethrin	1
Diazinon	0.2
Dimethomorph	20
Etoxazole	1.5
Fenhexamid	10
Fenpyroximate	2
Flonicamid	2
Hexythiazox	2
Fludioxionil	30
Imidacloprid	3
Kresoxim-methyl	1
Malathion	5
Metalaxyl	15
Methomyl	0.1
Myclobutanil	9
Naled	0.5
Oxamyl	0.2
Pentachloronitrobenzene	0.2
Permethrin	20
Phosmet	0.2
Piperonylbutoxide	8

Name	Maximum Contaminant Level (MCL) in ppm
Prallethrin	0.4
Propiconazole	20
Pyrethrins	1
Pyradiben	3
Spinetoram	3
Spinosad	3
Spiromesifen	12
Spirotetramat	13
Tebuconazole	2
Thiamethoxam	4.5
Trifloxystrobin	30

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483(L) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:480 (April 2021), LR 48:1291 (May 2022), amended LR 48:2982 (December 2022).

§523. Consumable Hemp Products Labeling Requirements: Medical Claims Prohibited

A. No product labeling or advertising material for any consumable hemp product sold or otherwise distributed in the state of Louisiana may bear any implicit or explicit medical claims.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:360 (March 2020), LR 48:1291 (May 2022).

§525. Consumable Hemp Products Labeling Requirements: Dietary Supplements Prohibited

A. No consumable hemp product may be marketed as a dietary supplement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:360 (March 2020), amended LR 48:1291 (May 2022).

§527. Consumable Hemp Products Labeling Requirements: Marketing for Inhalation Prohibited

A. No hemp flower consumable product may be marketed for inhalation purposes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 47:480 (April 2021), amended LR 48:1291 (May 2022).

§529. Consumable Hemp Products Packaging Requirements: Hemp Flower Packaging

A. Hemp flower consumable products for registration must be packaged in tamper-resistant packaging or with tamper-evident seals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:1291 (May 2022).

§531. Consumable Hemp Products Labeling Requirements: Adult-Use Products

A. Any product meeting the definition of an "adult-use consumable hemp product" must bear a label statement to this effect.

B. Products registered prior to the effective date of this rule that do not bear the statement required by Subsection A may be sold until July 1, 2023.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2983 (December 2022).

§533. Consumable Hemp Products Labeling Requirements: Serving Sizes and THC Content

A. Labeling must clearly indicate the amount of THC per serving in a product, the serving size, and the number of servings per package.

B. Serving sizes must be delineated by means of one of the following acceptable methods:

1. provision of a measuring device with the packaging;

2. markings on the label or package that indicate the amount of a serving;

3. use of discrete units (e.g., tablets, capsules, gummies, et cetera).

C. Products registered prior to the effective date of this rule that do not meet the requirements of this Section may be sold until July 1, 2023.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2983 (December 2022).

§535. Penalties for Violations of Requirements to Register Consumable Hemp Products [Formerly §531]

A. Any person who violates the provisions requiring registration of industrial-hemp-derived cannabidiol products is subject to the penalties provided for by R.S. 3:1484 and other sanctions as provided for by the State Food, Drug, and Cosmetic Law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:480 (April 2021), LR 48:1291 (May 2022), LR 48:2983 (December 2022).

§537. Exemptions [Formerly §533]

A. Consumable hemp products that have been produced in accordance with R.S. 40: 1046 or that are Food and Drug

Administration (FDA)-approved pharmaceuticals are not subject to the requirements of this regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:480 (April 2021), LR 48:1291 (May 2022), LR 48:2983 (December 2022).

Chapter 6. Tolerances for Pesticides in Food

§601. CFR 193 Adoption by Reference [Formerly 49:2.3100]

A. The Department of Health and Hospitals/ OPH hereby adopts the federal regulations for Tolerances for Pesticides in Food administered by the Environmental Protection Agency, as found in 21 CFR 193 dated April 1, 1984.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 11:775 (August 1985).

Chapter 7. Flour and Bread Regulations

§701. Labeling of Enriched Flour [Formerly 49:2.510]

A. All enriched flour shall be labeled as "Enriched Flour".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§703. Enrichment Standards; Label Declaration of Optional Ingredients [Formerly 49:2.511]

A. It shall be unlawful for any person to manufacture, mix, compound, sell or offer for sale, for human consumption in this State, any flour as defined by Act No. 202 of 1942 unless:

1. It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 13.0 milligrams and not more than 16.5 milligrams of iron (Fe);

2. Vitamin D may be added in such quantity that each pound of the finished enriched flour contains not less than 250 U.S.P. units and not more than 1,000 U.S.P. units of Vitamin D.

3. Calcium may be added in such quantity that each pound of the finished enriched flour contains not less than 500 milligrams and not more than 625 milligrams of calcium (Ca), except that enriched flour may be acidified with monocalcium phosphate irrespective of the minimum limit for calcium (Ca) herein prescribed;

4. It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

5. Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (1) and (2) of this regulation may be added in a harmless carrier which does not impair the enriched flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

6. when any of the optional ingredients permitted by paragraphs (2), (3) and (4) of this regulation are added, the kind and amount shall be plainly stated on the label.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§705. Labeling of Enrichment Ingredients; Average Daily Requirement [Formerly 49:2.512]

A. When any reference is made on the labeling of flour to the kinds and amounts of enriching ingredients which have been added, such reference shall be limited to show the proportion of the average adult's daily requirements of such substances.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§707. Labeling Claims; Amount of Added Chemicals [Formerly 49:2.513]

A. Enriched flour labels shall not contain claims regarding physiological or therapeutic effects of enriching ingredients nor information concerning other mineral or vitamins; except, that self-rising flour or phosphated flour shall list the kinds and amounts of added chemicals as required by Act 181 of 1936 (Self-Rising Flour Law).

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§709. Certificate of Intent; Sale of Unenriched Flour [Formerly 49:2.514]

A. Bakers or other commercial secondary processors purchasing unenriched flour shall furnish the seller with a certificate of intent, certifying that the unenriched flour will be used only in the production of flour or bread enriched within the purchaser's establishment in com pliance with the law and these regulations. The certificate shall show, in addition to any other information contained therein, the name and address of the purchaser, the name and address of

the seller, the effective date, and the purchase or purchases covered by the certificate.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§711. Certificate of Intent; Distribution of Copies [Formerly 49:2.515]

A. The certificate shall be made in triplicate. The seller shall be given one copy, one copy shall be forwarded to the department and one shall be retained by the purchaser.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§713. Types of Certificates of Intent [Formerly 49:2.516]

A. The certificate shall be in one of two forms:

1. A continuing certificate covering all purchases from each seller for an indefinite period of time and specifying that the certificate shall remain in force until notice is given in writing of its cancellation.

2. A certificate covering a single purchase order, in which case the certificate shall specify the exact quantity of flour covered by the certificate, the trade or brand names, or other identifying marks on the flour containers, and any other information needed to identify the flour as that covered by the certificate.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§715. Enrichment Labeling of Wrapped Bread [Formerly 49:2.517]

A. All enriched bread, when wrapped, shall be labeled "Enriched Bread".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§717. Unlawful Manufacture, Mixing Compounding, Sale of Bread; Enrichment Standards [Formerly 49:2.518]

A. It shall be unlawful for any person to manufacture, mix, compound, sell, or offer for sale for human consumption in this state, any bread as defined by Act No. 202 of 1942 unless:

1. it contains in each pound not less than 1.1 milligrams and not more than 1.8 milligrams of thiamine, not less than 0.7 milligrams and not more than 1.6 milligrams of riboflavin, not less than 10.0 milligrams and not more than 15.0 milligrams of niacin or niacinamide, not less than 8.0 milligrams and not more than 12.5 milligrams of iron (F e);

2. vitamin D may be added in such quantity that each pound of the finished food contains not less than 150 U.S.P. Units and not more than 750 U.S.P. Units of Vitamin D;

3. calcium may be added in such quantity that each pound of the finished food contains not less than 300 milligrams and not more than 800 milligrams of calcium (Ca);

4. each such food may also contain as an optional ingredient wheat germ or partly defatted wheat germ; but in no case is the total quantity thereof more than the maximum which may be present as a result of the use of enriched flour.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§719. Nutritional Information Labeling [Formerly 49:2.519]

A. When any reference is made on the labeling of bread to the kinds and amounts of enriching ingredients which have been added, such reference shall be limited to show the proportion of the average adult's daily requirements of such substances.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§721. Bread Labeling, Physiological or Therapeutic Claims [Formerly 49:2.520]

A. Enriched bread labels shall not contain claims regarding physiological or therapeutic effects of enriching ingredients nor information concerning other minerals or vitamins.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§723. Establishment Inspection Authority [Formerly 49:2.521]

A. Any flour mill, flour warehouse, wholesale flour dealer's establishment, or any other place where flour may be milled, stored, distributed or offered for sale, or any bakery, bakery warehouse or secondary flour processing establishment in Louisiana shall be subject to inspection by an authorized representative of the department at any reasonable time during working hours to determine whether flour or bread stocks are in compliance with the law or these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

Chapter 9. Meat and Meat Products Regulations

§901. Use of Brand or Trade Names [Formerly 49:3.000]

A. No person shall make, prepare, affix, or use, or cause to be made, prepared, affixed or used on any meat or meat product any brand or trade name or any abbreviation, or copy or representation thereof, except in compliance with these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§903. Product Marking [Formerly 49:3.010]

A. No person shall remove or cause to be removed from any slaughter house, meat packing plant, sausage kitchen or other meat product establishment any article which these regulations require to be marked in any way, unless the same is clearly and legibly marked in compliance with these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§905. Marking of Carcasses [Formerly 49:3.020]

A. Each carcass at time of slaughter, or as soon thereafter as possible, shall be marked with the establishment's permit number. Each principal part shall be likewise marked before it leaves the establishment in which it was slaughtered.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§907. Prepared Sausage, Permit Number Required [Formerly 49:3.030]

A. Prepared sausage and other meat food products in casings of the ordinary "ring" variety or larger, shall bear on the casings the permit number of the establishment. Prepared sausage and other meat food products in casings of the smaller varieties shall have imprinted or stamped on the casings on permit number to each chain, or two or more such marks to each bunch, except in cases where such smaller varieties of sausage and products leave the establishment completely enclosed in properly labeled cartons or wrappers, having a capacity of ten pounds or less and containing a single kind of product. All markings may be omitted from sausage and other meat food products in casings when these articles are to be packed in sealed cans.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§911. Imitation Sausage, Must be Bolding Stamped [Formerly 49:3.0301]

A. Meat food products in casings, other than sausage, which possess the characteristics of or resemble sausage, when sold in packages of more than two pounds net weight, shall bear on each line, or at least once in each twelve inches if not sold in link form, the word "imitation" prominently displayed; provided:

1. that such products in casings as coppa, capacola, lachschinken, bacon, pork loins, pork shoulder butts, and like cuts of meat which are prepared without added substances other than curing materials or condiments; and

2. meat rolls, bockwurst, and similar products which do not contain cereal or vegetables; and

3. headcheese, souse, scrapple, sulze, blood pudding and liver pudding in casings; need not be marked on the casing with the word "imitation"; and that other products in casings such as loaves, luncheon meats, and chili con carne, may bear on each link or piece the true name of the product in lieu of the word "imitation"; provided also, that all markings on the casings may be omitted when the articles are placed in sealed cans processed in the establishment, *and* the containers are properly labeled in compliance with Act 142 of 1936 as amended.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§913. Sausage, Binders and Extenders [Formerly 49:3.040]

A. When cereal, vegetable starch, dried skim milk, soya flour, and/or other approved binders and extenders are added to sausage within the limits prescribed under §974 and §975, the product shall be marked with the specific name of each such added ingredient, as, for example, "cereal added," "potato flour added," "cereal and potato flour added," "dried skim milk added," and so forth, as the case may be. On sausage of the small varieties the marking prescribed in this regulation may be limited to links bearing the permit number.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§915. Sausage, Artificial Coloring [Formerly 49:3.0401]

A. When meat food products are placed in casings to which artificial coloring is applied under §972, the articles shall be legibly and conspicuously marked by stamping or printing on the casings, or securely affixing to the articles, the printed words "artificially colored;" provided:

1. that if the casing is removed from the meat product coloring on the surface of the meat product, the article from which the casing has been removed shall be marked by stamping directly thereon, or by securely affixing thereto, the printed words "artificially covering, the coloring shall be of a kind and shall be so applied as colored;"

2. that when the casing is colored prior to its use as a covering, the coloring shall be of a kind and shall be applied as not to be transferable to the meat food product enclosed therein, and the casing shall be marked with the words, prominently displayed "casing colored;"

3. that sausage of smaller varieties, such as frankfurters, when sold in labeled bulk containers, shall bear the words "artificially colored" at least once on each 1 1/2 pounds of product;

4. that when such meat product is distributed in an immediate or true container of a type and size customarily sold intact at retail the declaration of coloring on the label of the container shall be sufficient.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§917. Meat Products, Listing of Ingredients [Formerly 49:3.0402]

A. A meat product made from two or more ingredients shall bear a list of the ingredients, giving their common or usual names arranged in the order of their predominance; except that spices, flavorings (including essential oils, oleoresins, and other spice extractives) and colorings may be designated as "spices," "flavorings," and "colorings" without naming each. The list of ingredients shall be applied legibly and securely to the meat product by means approved by the department, such as stamping, printing, or the use of paper bands, or tied, in paper or fabric flaps on stuffed sausage, or tissue strips on loaf, like articles; provided: that meat products for which definitions and standards of identity have been prescribed by regulations, and which conform to such definitions and standards, and which bear the names specified in the definition and standards, together with such declaration of optional ingredients and other labeling features as are required in the applicable definitions and standards, need not bear lists of ingredients. Provided, further, that sausages of the smaller varieties, such as frankfurters, wieners and fresh or smoked pork sausage and bockwurst, shall bear the list of ingredients at least once on each 1 1/2 pounds of product; and provided, further, that when such meat product is distributed in an immediate or true container of a type and size customarily sold intact at retail, the list of ingredients on the label of the package shall be sufficient.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§921. Product Definitions and Standards [Formerly 49:3.0403]

A. Meat. The edible part of the muscle of cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin sinew, nerve, and blood vessels which normally accompany the muscle tissue, and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout or ears.

B. Meat By-Product. Any edible part other than meat which has been derived from one or more cattle, sheep, swine, or goats.

C. Meat Product or Meat Food Product. Any article of food, or any article intended for or capable of being used as human food which is derived or prepared, in whole or in substantial and definite part, from any portion of any cattle, sheep, swine, or goat, except such articles as organotherapeutic substances, meat juice, meat extract, and the like, which are only for medicinal purposes, and are advertised only to the medical profession.

D. The product titled hamburger shall be comprised of wholesome comminuted or ground beef, containing not more than 30 percent beef fat by weight, with or without seasoning (properly labeled). With proper labeling declaration, optional ingredients are monosodium glutamate, salt, sugar, seasonings, spices ascorbic acid, sodium asorbate, erythorbic acid, sodium erythorbate, any other acceptable food additive approved by the department and added water not to exceed 1 percent. No added coloring shall be permitted.

E. Ground Meat. The product titled ground meat shall consist of wholesome comminuted or ground meat from beef, veal, swine, sheep, or goat, individually or collectively, in any combination whatsoever, provided that each specie shall be listed in the ingredient statement in correct order of descending predominance. When consisting of one specie only the product shall be titled ground beef, ground pork, or whatever the case might be. Ground meat shall contain not more than 30 percent meat fat by weight, unless said product is comprised wholly of pork meat, in which case the maximum allowable fat content shall be 50 percent. No added coloring or water shall be perm fitted.

F. Pork Sausage is the sausage product prepared from wholesome pork meat, comprising not more than 50 percent pork fat and not more than 3 percent added water. With proper labeling declaration, optional ingredients permitted are monosodium glutamate, salt, sugar, seasonings, spices,

ascorbic acid, sodium ascorbate, erythorbic acid, sodium erythorbate, water or any other additives approved by the department. The use of coloring is prohibited.

G. Specially Meat Products, including patties and products which have been subjected to a particular processing operation such as chopping, grinding, or comminution, such as steaks, chops, steakettes and choppettes, which names in natural form indicate a solid piece of meat, must bear a title descriptive of the product reflecting the processing to which it has been subjected, e.g. chopped veal steaks; or must bear a statement of fact contiguous to the name of the product, such as "chopped, formed and frozen." With proper labeling declaration, optional ingredients permitted are monosodium glutamate, salt, sugar, seasonings, spices, ascorbic acid, sodium ascorbate, erythorbic acid, sodium erythorbate, or any other additives approved by the department. No added coloring shall be permitted. Further, if extenders or binders, such as cereal, vegetable starch, vegetable flour, soya flour, nonfat dry milk, soya protein concentrate or any other similar product approved by the department are added to the product, the individual and collective amount shall not exceed 3.5 percent, and a statement of fact, such as, "cereal added" or "dry skim milk added," or whichever the case may be, shall appear immediately below and contiguous to the tile in letters of not less than one—half the size of the title, in addition to appropriate inclusion of said ingredients in the ingredient statement. Added water shall not exceed 1 percent.

H. Products titled "liver loaf", "liver paste", "liver cheese", "liver pudding", "liver spread" and the like shall contain not less than 30 percent of liver computed on the weight of fresh liver.

I. The preparation of cooked cured products such as hams, pork shoulders, pork shoulder picnics, pork shoulder butts, and pork loins, either by moist or dry heat, shall not result in the finished cooked articles weighing more than the fresh uncured product; that is, the weight of the finished cooked article plus the weight of the skin, bones, fat, and trimmings removed during the preparations shall not exceed the weight of the fresh uncured product. Such product, under appropriate labeling declaration, may contain up to 10 percent added water in which case the statement "water added" shall appear immediately below and contiguous to the title in type of not less than one—half the size of that used for the title. Products containing added water in excess of 10 percent shall be titled "imitation" and the word "imitation" shall appear immediately before and in type of the same size, style, and prominence as the name of the product being imitated.

J. Formulation and labeling of specialty meat products, such as boudin, shall be approved as provided is §944.

K.1.Fish Sausage or Crayfish Sausage is the sausage product prepared from wholesome, edible fish or crayfish species, comprising not more than 50 percent beef or pork suet and not more than three percent added water. Edible fish species are any species of fish that are considered to be edible and non-toxic to humans by demonstrable, scientific facts or scientific opinion. With proper labeling declaration, optional ingredients permitted are monosodium glutamate, salt, sugar, seasonings, spices, ascorbic acid, sodium ascorbate, erythorbic acid and sodium erythorbate. Fish sausage or crayfish sausage may be colored with a coloring agent approved by the Department of Health and Hospitals/OPH, Food and Drug Unit specifically for that purpose.

2. Fresh fish and crayfish received shall be inspected and adequately washed before processing. Only sound, wholesome fish and crayfish, free from adulteration and organolepticlly detectable spoilage, shall be processed.

3. The name of the product described in Subsection K above shall be "fish sausage" or "crayfish sausage" and all fish sausage and crayfish sausage shall be labeled as such.

L.1. “Nutria” or “nutria meat” is the edible part of the muscle of the nutria which is skeletal and shall not include muscle that is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without accompanying and overlying fat, and the portions of bone, skin sinew, nerve and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing.

2. “Nutria meat product” is any article of food, or any article intended or capable of being used as food which is derived or prepared, in whole or in substantial definite part, from the skeletal muscle of nutria.

3. “Nutria sausage” is the coarse of finely comminuted meat food production prepared from nutria meat in combination with one or more kinds of meat or meat and meat by-products, containing various amounts of water and usually seasoned with condimental substances, and frequently cured. Nutria sausage shall contain greater than 50 percent nutria meat in combination with other meat or meat and meat by-products. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of nutria sausage which is not cooked in an amount not to exceed 3 percent of the total ingredients of the formula.

a. “Uncooked, smoked nutria sausage” is nutria sausage that is smoked with hardwood or other approved nonresinous materials. Smoked nutria sausage shall contain greater than 50 percent nutria meat in combination with beef, pork or poultry meat or beef, pork, or poultry meat by-products. To facilitate chopping or mixing, water, or ice may be used in an amount not to exceed 3 percent of the total ingredients used. Nutria, beef, pork and poultry meat ingredients as well as all other ingredients shall be designated in the ingredient statement on the label of such sausage as required by §245 of the food regulations.

b. “Cooked nutria sausage” is nutria frankfurter nutria frank, nutria further, nutria hot-dog, nutria wiener and similar products which are comminuted, semisolid sausages prepared from raw skeletal nutria muscle meat alone or in combination with beef meat, pork meat, or poultry meat and

seasoned and cured, using one or more of the curing agents in accordance with 9 CFR 318.7(c). They may or may not be smoked. The finished products shall contain not less than 50 percent nutria meat and not more than 30 percent fat. These sausage products may contain only phosphates approved under 9 CFR 318. Such products may contain raw or cooked poultry meat not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and mechanically separated (species) used in accordance with 9 CFR 319.6. Nutria, beef, pork and poultry meat ingredients as well as all other ingredients shall be designated in the ingredient statement on the label of such sausage as required by 49:2.0220 of the food regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended LR 10:1035 (December 1984), amended by the Department of Health and Hospitals, Office of Public Health, LR 22:29 (January 1996).

§923. Sausage, Binders or Extenders Content [Formerly 49:3.0404]

A. When meat products are placed in casings, e.g. sausages, they shall contain not more than 3.5 percent, individually and collectively, or cereal, vegetable starch, starchy vegetable flour, dried milk or dried skim milk, soya flour or any other binders or extenders. Sausages containing binders or extenders in excess of 3.5 percent by weight shall be labeled as an imitation as provided in the Louisiana Food, Drug and Cosmetic Law, R.S. 40:608 (3). If sold in packages of more than two pounds net weight, each link of sausage shall be legibly and conspicuously marked by stamping or printing on the casing the word "Imitation," in addition to the required complete labeling on the package. When not sold in link form, the word "Imitation" shall appear at least once on each twelve inches of sausage.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§925. Meat and Meat Product Labeling [Formerly 49:3.0500]

A. When any meat product is placed in any can, pot, tin, canvas, or other receptacle or covering constituting an immediate or true container, there shall be affixed to such container or covering a label as hereinafter described; except that:

1. plain wrappings for fresh meat, such as dressed carcasses and principal parts thereof, which are used solely to protect the product against soiling or excessive drying during transportation or storage need not bear a label;

2. uncolored transparent coverings, such as cellophane or polyethylene sheeting, which bear no printed or graphic matter, and which enclose any unpacked or packaged meat or meat product bearing all required markings and/or labeling are clearly legible through such coverings; and

3. animal and transparent artificial casings bearing no marks or printed features other than those required in the foregoing regulations need not bear additional labeling.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§927. Labeling of Folders [Formerly 49:3.0501]

A. Folders and similar coverings made of paper or like material, which do not completely enclose the product and which bear any printed word or statement shall possess all features required on a label for an immediate or true container.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§929. Labeling Only Wholesome Products [Formerly 49:3.0502]

A. No container or covering which bears or is to bear, a label shall be filled in whole or in part except with articles which are sound, healthful, wholesome, and fit for human food, and which are strictly in accordance with the statements on the label.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§931. Definitions of Labels [Formerly 49:3.060]

A. Labels within the meaning of these regulations shall include any printed, stamped, lithographed, embossed or other marking on any sticker, seal, tie-in, band-around, tissue-strip, fabric-flap, wrapper, or receptacle used on any meat or meat product.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§933. Labels, Mandatory Information [Formerly 49:3.0601]

A. Labels shall contain prominently and informatively displayed:

1. the true name of the meat or meat product;

2. the word "ingredients" followed by a list of the ingredients when the meat or meat product is made from two or more ingredients;

3. the name and place of business of the manufacturer, packer or distributor;

4. an accurate statement of the quantity of contents; and

5. the Louisiana department permit number of the establishment, the federal inspection legend and establishment number, or the official stamp of any approved state, parish or municipal meat inspection service, on that portion of the label featuring the name of the meat or meat product, or, on the principal display panel, when there are two or more panels; provided: that the name and place of business of the manufacturer, packer or distributor, and the statement of the quantity of contents may be omitted from the labels for meat or meat products not required to be labeled under regulation §925; and provided further, that the permit number or establishment number may be omitted from labels on cartons used outer containers of edible fats, such as lard or olemargarine, when such articles are enclosed in wrappers which bear the department permit number or the federal, state, parish or municipal inspection legend and establishment number.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§935. Label, Common or Usual Name [Formerly 49:3.0700]

A. The name of a meat or meat product used on any labeling shall be the common or usual name, if any there be, and one which clearly and completely identifies the article. Any meat or meat food product which has been prepared by salting, smoking, drying, cooking, chopping and the like shall be so described on the label unless the name of the article implies, or the manner of packaging shows, that the meat or meat product was subjected to such procedure or procedures. The unqualified terms, "meat," "meat by-product," "meat food product," and terms common to the meat industry but not to the consumer, such as "picnic," "butt," "cala," "square," "loaf," "spread," "delight," "roll," "plate," "luncheon," and "dairy," shall not be used as names of articles unless accompanied by terms descriptive of the meat or meat product or with a list of the ingredients.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§937. Label, List of Ingredients [Formerly 49:3.0701]

A. The list of ingredients shall appear as part of, or in addition to, the true name of the product, and shall show the common or usual names of the ingredients arranged in the order of their predominance; except that spices, flavorings (including essential oils, oleoresins, and other spice extractives) and colorings may be designated as "spices," "flavorings," and "colorings" without naming each. The name of an ingredient shall not be a collective name but shall be specific, as, for example, "beef," "pork," "beef tripe," "beef hearts," "sheep livers," "pork snouts," "flour," "corn flour," "potato flour," "water," "dried skim milk," "tomato puree," and "beef broth;" provided, that when the label bears the designation “compound," or "shortening," the term "animal and vegetable fats" or "vegetable and animal fats" may be used to designate the ingredients of mixture of such edible fats whether unhardened or hardened singly or as a mixture.

1. "Animal fats" as used herein means sound, healthful, wholesome fat derived from cattle, swine, sheep or goats.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§939. Label, Establishment Must Name [Formerly 49:3.0702]

A. The name of the establishment, the operator of which has been granted a department permit to operate, may appear without qualification upon the label or container of an article prepared in the establishment so named. When an article is prepared in such an establishment for a person, firm or corporation unconnected with or possessing no authority under such permit and the name of such person, firm or corporation is to appear on the label or container thereof, the name so appearing shall be qualified by a phrase which reveals the connection such person, firm or corporation has with the food, as, for example, "prepared for, distributed by."

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§941. Label, Quantity of Contents [Formerly 49:3.0703]

A. The statement of quantity shall represent in terms of avoirdupois weight or liquid measure the quantity of meat or meat product in the package (exclusive of materials packed with it). When no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure if the product is liquid, or in terms of weight if the meat or meat product is solid, semi-solid, viscous, or a mixture of solid and liquid. Unless the statement is so qualified as to show that it expresses the minimum quantity, it shall be assumed to express the actual quantity. When the statement expresses the minimum quantity, no variation below the stated minimum shall be no greater than consistent with filling the container in accordance with good commercial practice. When the statement expresses actual quantity, variations incident to packing in accordance with good commercial practice shall be allowed, but the average shall not be less than the quantity stated; provided, that packages of meat or meat products having a capacity of less than 1/2 ounce avoirdupois or less than 1/2 fluid ounce shall not be required to be labeled with the statement of the quantity of contents.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§942. Label, Permit or Establishment Number [Formerly 49:3.0704]

A. The department permit number, federal establishment number or official number of any approved state, parish or municipal meat inspection service shall be embossed on all sealed metal containers of meat or meat products, except that such containers which bear lithographed labels in which the state permit number, federal establishment number, or official number of any approved state, parish or municipal meat inspection service is incorporated need not have the number embossed thereon. Labels shall not be affixed to containers so as to obscure the embossed state permit or federal establishment number.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§943. Label, Standardized Product [Formerly 49:3.0705]

A. When any meat or meat product is labeled with the name of or is represented as, an article for which definitions and standards of identity have been prescribed by regulation, the product shall conform to such definitions and standards.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§944. Label Approval [Formerly 49:3.0800]

A. No label shall be used on any meat or meat product until the label has been approved in its final form by the department or by the federal agency having supervision over meats or meat products moving in interstate traffic.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§945. Label Approval, Product Formula [Formerly 49:3.0801]

A. Each copy of the label of any meat or meat product made from two or more ingredients shall be accompanied by a statement showing the kinds and percentages of the ingredients and mode of preparation. Approximate proportion of meat or meat product ingredients may be given when the proportion of meat or meat products may vary from time to time, if the limits of variation are stated.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§946. Label Approval, Inserts, Tags, etc. [Formerly 49:3.0802]

A. Inserts, tags, liners, pasters, and other like devices containing printed or graphic matter and for use on, or to be placed within containers and coverings of meat or meat products, shall be submitted for approval in the same manner as provided for labels in §944.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§947. Label, Shipping Containers [Formerly 49:3.0803]

A. Stencils and box dyes may be used on shipping containers, including tierces, barrels, drums, boxes, crates and large-size fiberboard containers, provided the markings are applicable to the contained product and are not false or deceptive.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§948. Labels Use Only on Products for Which Approved [Formerly 49:3.0900]

A. Labels shall be used only on products for which they are approved. They shall not be applied to any meat or meat product the container or covering of which is so made, formed or filled as to be deceptive or misleading.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§949. Labels, False or Deceptive Names Prohibited [Formerly 49:3.1000]

A. No meat or meat product, and no container thereof, shall be labeled with any false or deceptive name.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§950. Labels, Imitation Products [Formerly 49:3.1001]

A. The label for any meat or meat product which has been made in imitation of another food shall bear the word "imitation" immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and, immediately thereafter, the words "made from" or

equivalent statement and the names of the ingredients arranged in the order of their predominance.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§951. Labels, False Impressions Prohibited [Formerly 49:3.1002]

A. No statement, word, picture, design or device which conveys any false impression or gives any false indication of origin or quality shall appear on any label; for example.

1. Terms having geographical significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word "style", "type", or "brand" as the case may be, in the same size and style of lettering as in the geographical term, and accompanied with a prominent qualifying statement identifying the country, state, territory, or locality in which the product is prepared, using terms appropriate to effect the qualification. When the word "style" or "type" is used, there must be a recognized style or type of meat or meat product identified with and peculiar to the locality represented by the geographical term and the meat product must possess the characteristics of such style or type; provided, that the terms which have come into general usage as trade names and have been so approved by the department or federal agency having jurisdiction may be used without the qualifications provided for in this paragraph. The terms "Frankfurter", "Vienna", "Bologna", "Braunshweiger", "Thuringer", "Genoa", and their modifications, as applied to sausages; the terms "Brunswick" and "Irish" as applied to stews; and the term "Boston" as applied to pork shoulder butts, are recognized as generic names and need not be accompanied with the word "style", "type", or "brand", or a statement identifying the locality in which prepared.

2. The word "ham" without any prefix indicating the species of animal from which derived, shall be used on labels only in connection with pork hams. Ham shanks as such or ham shank meat as such, or the trimmings accruing in the trimming and shaping of hams, shall not be labeled "ham" or "ham meat" without qualification. When used in connection with a chopped product the term "ham" or "ham meat" shall not include the skin.

3. The word "fresh" shall not be used on labels to designate any meat or meat product which contains any sodium or potassium nitrate, sodium or potassium nitrite, or any other preservative approved by the department, or which has been salted, pickled, or brined for preservation. Further, the use of sodium nitrite, potassium nitrite, sodium nitrate or potassium nitrate or any combination of nitrate or nitrite, shall not result in the presence of more than 200 p.p.m. nitrite in the finished product. Supplies of nitrates and nitrites and mixtures containing them, shall be kept securely under the care of a responsible employee of the establishment. The specific nitrate and nitrite content of such supplies must be known and clearly marked accordingly.

4. Such terms as "meat extract", or "extract of beef", without qualification, shall not be used on labels in connection with products prepared from organs or parts of carcasses other than fresh meat. Extracts prepared from any parts of the carcass other than fresh meat shall not be labeled "meat extract" but may be labeled with the true name of the parts from which prepared. In the case of extract in the fluid form, the word "fluid" shall also appear on the label, as, for example, "fluid extract of beef".

5. Such terms as "farm", "country", and the like shall not be used on labels in connection with meat and meat products unless such meat or meat products are actually prepared on the farm or in the country. However, if the articles are prepared in the same way as on the farm or in the country, these terms, if qualified by the word "style," in the same size and style of lettering, may be used. Sausage containing cereal shall not be labeled "farm style" or "country style," and lard not rendered in an open kettle shall not be designated as "farm style" or "country style".

6. The term "leaf lard" is applicable only to lard prepared from fresh leaf fat.

7. Oil, stearin, or stock obtained from beef or mutton fats, rendered at a temperature about 170° F, shall not be designated as "oleo oil," "oleo Stearin," or "oleo stock," respectively.

8. When any meat or meat product is enclosed in a container along with a packing substance such as brine, vinegar, or agar—agar jelly, a declaration of the packing substance shall be printed prominently on the label in connection with the name of the product, as for example, "frankfurters packed in brine," "beef tongue packed in agar—agar jelly," or "lamb tongue packed in vinegar," as the case may be. The statement of the quantity of contents shall represent the weight of the drained product when removed from the container to the exclusion of packing substance.

9. The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any establishment from the requirement that its label shall not be misleading in any particular.

10. The words "spice", "spices" and "spiced", without qualification, shall not be used unless they refer to genuine natural spices.

11. When lard or hardened lard is mixed with rendered pork fat, the mixture shall be designated as "rendered pork fat", or "hardened rendered pork fat", as the case may be.

12. When not more than 20 percent of beef fat, mutton fat, oleo stearin, vegetable stearin, or hardened vegetable fat is mixed with lard or with rendered pork fat, there shall appear on the label, next to and in the same style and size of lettering as the name of the product, the words "beef fat added", "mutton fat added", °oleo stearin added", "vegetable stearin added", or "hardened vegetable fat added", as the case may be.

13. When cereal, vegetable starch, soya flour, dried skim milk and/or other approved binders or extenders are added to sausage within the limits prescribed under §974, there shall appear on the label in a prominent manner, next to the name of the product, the name of each such added ingredient, as, for exam pie, "cereal added," "with cereal, "potato flour added," "cereal and potato flour added," "dried skim milk added," "cereal and dried skim milk added," as the case may be.

14. Tierces, barrels, and half—barrels containing lard, rendered pork fat and mixtures of edible fats com posed in whole or in part of animal fats shall, immediately before or immediately after filling, be legibly marked on one end and on the side near that end with the true name of the product. Pails, tubs, drums and similar containers of such products, shall bear the true name of the product on the side at the time of filling.

15. The term "meat" and the name of particular kinds of meat, such as beef, veal, mutton, lamb and pork, shall not be used in such a manner as to be misleading or deceptive.

16. The terms "shankless" and "hockless" shall apply only to hams and pork shoulders from which the shank or hock has been completely removed, thus eliminating entirely the tibia and fibula, or radius and ulna, respectively together with the overlying muscle, skin and other tissue.

17. Products labeled "chili con carne" shall contain not less than 40 percent of meat, computed on the weight of the fresh meat. Hearts, cheek meat, head meat or seasoned meat may be used to the extent of 25 percent of the meat ingredient under specific declaration on the label. The mixture shall not contain more than 8 percent of cereal.

18. Products labeled "chili con carne with beans" shall contain not less than 25 percent of meat computed on the weight of the fresh meat. Hearts, cheek meat, head meat or seasoned meat, may be used to the extent of 25 percent of the meat ingredient under specific declaration on the label.

19. Products labeled "corn beef hash" shall contain not less than 35 percent of corned beef, based on the weight of the cooked and trimmed beef.

20. The term "gelatin" as used on the labels of meat or meat products shall mean:

a. the jelly prepared by cooking pork skin, tendons, or other connective tissue from wholesome animals, and

b. dry commercial gelatin or the jelly resulting from its use.

21. The term "vegetable fat" shall be applicable to vegetable oil or stearin, or a combination of such vegetable oil or stearin; whereas the term "vegetable oil" and "vegetable stearin" shall be applicable only to the oil and the stearin, respectively.

22. The term "baked" shall apply only to meat or meat products which have been cooked by the direct action of dry heat and for a sufficient time to permit the meat or meat products to assume the characteristics of baked articles, such as the formation of a brown crust on the surface, rendering out of surface fat, and the caramelization of any sugar, that may have been applied.

23. Coverings for meat or meat products shall not be of such color, design or kind as to be misleading or deceptive with respect to color, quality or kind of meat or meat products to which applied. For example, transparent or semi-transparent coverings for such articles as sliced bacon or pork sausage shall not bear lines or other designs of red or other color which can give a false impression of leanness of the meat or meat product, or shall not have an amber or smoked color of such shade, degree, or intensity as to give a false impression with respect to smoking or degree of smoking of the meat or meat product.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§952. Meat Product Labeling Artificial Coloring, Flavoring or Preservative [Formerly 49:3.1100]

A. Any meat product which bears or contains any artificial coloring, artificial flavoring or preservative shall bear labeling stating that fact.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§953. Edible Fats Labeling Artificially Colored [Formerly 49:3.1101]

A. Artificial coloring of edible fats shall be declared on the label in a prominent manner and contiguous to the name of the product by the words "artificially colored".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§954. Meat Product Labeling, Artificial Coloring [Formerly 49:3.1102]

A. When any meat product is placed in casings to which artificial coloring is applied under §972, there shall appear on the label in a prominent manner and contiguous to the name of the meat product the words "artificially colored", provided, that if the casing is removed from the meat product at the place of manufacture and there is evidence of the artificial coloring on the surface of the meat product, there shall appear on the label in a prominent manner and contiguous to the name of the meat product the words "artificially colored"; and provided further, that when the casing is colored prior to its use as a covering for any meat or meat product, there shall appear on the label in a prominent manner and contiguous to the name of the meat or meat product the words "casing artificially colored".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§955. Meat of Meat Product Labeling, Artificially Flavored [Formerly 49:3.1103]

A. When any artificial flavoring is added to meat or meat products, there shall appear on the label in prominent letters and contiguous to the name of the meat or meat product the words "artificially flavored".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§956. Meat or Meat Product Labeling, Frozen Products [Formerly 49:3.1104]

A. Products sold in the frozen state shall be so labeled and the cautionary statement "Keep frozen—Do not refreeze" shall be prominently displayed on the principal panel. Cooked or processed meat products requiring refrigeration shall bear the statement "Perishable—Keep refrigerated". Perishable products shall be stored or displayed under refrigeration of 45° F. or below.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§957. Labeling, Reuseable Containers [Formerly 49:3.1200]

A. All stencils, marks, labels, or other devices on previously used containers whether relating to any meat or meat product or not, shall be removed or obliterated before such containers are reused for any meat or meat product, unless such stencils, marks, labels or devices correctly indicate the article to be packed therein and such containers have been prepared for reuse in compliance with R.S. 40:681-40:689 (Secondhand Containers Law).

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§958. Labeling, Compliance Required [Formerly 49:3.1300]

A. All labeling of meat and meat products shall be in compliance with these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§959. Prohibited Acts: Labels, Use of in Compliance with Regulations [Formerly 49:3.1301]

A. No person shall affix or apply, or cause to be affixed or applied, any label to any article of meat or any meat product, or to any container thereof, except in compliance with these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§960. Prohibited Acts: Labeling, Must be in Compliance with Regulations [Formerly 49:3.1302]

A. No person shall fill or cause to be filled in whole or in part, any container with any article which is required by these regulations to bear a label, except in compliance with these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§961. Prohibited Acts: Removal of Product [Formerly 49:3.1303]

A. No person shall remove, or cause to be removed, from any slaughter house, meat packing plant, sausage kitchen or other meat product establishment, any meat or meat product bearing a label unless such label is in compliance with these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§962. Prohibited Act: Transfer of Labels for one Plant to Another [Formerly 49:3.1400]

A. Labels, wrappers and cartons bearing a permit number shall not be forwarded from one establishment to another, nor shall any establishment use any label, wrapper or carton bearing the permit number of any other slaughter house, meat packing plant, sausage kitchen, or other meat product plant.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§963. Meat and Meat Products, Must and Sound and Wholesome [Formerly 49:3.1500]

A. All meats and meat products, whether fresh or cured, shall be subject to inspection at any time during reasonable working hours, in order to determine whether the same are

sound, healthful, wholesome and fit for human food. If upon inspection any article is found to have become unsound, unhealthful, unwholesome, or in any way unfit for human food, the original mark stamp or label thereon shall be removed or defaced and the article condemned; provided that:

1. if an article becomes soiled or unclean by falling on the floor or in any other accidental way whereby the meat or meat product may be cleaned or trimmed to remove or repair all soiled areas;

2. if an article is found to have absorbed a foreign odor, contains mold or similar substance or, in the case of rendered animal fat, there is present tank water in the first stage of sourness, and the article is capable of being rehandled by approved methods to recondition it for food purposes if the necessary steps are taken immediately, such reconditioning may be permitted; provided that upon final reinspection if the article is found to be sound and wholesome it may be approved for human food; otherwise it shall be condemned and either destroyed or rendered into tankage.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§964. Meats and Meat Products, Refrigeration and Freezing [Formerly 49:3.1600]

A. All meats and meat products placed in refrigerators or freezers shall be in good condition. In case there is any doubt as to the soundness of any frozen meat or meat product, any authorized representative of the department may require the defrosting and inspection of a sufficient quantity thereof to determine its actual condition.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§965. Meat and Meat Products, Seizure [Formerly 49:3.1700]

A. All meat and meat products which are suspected on inspection of being unsound, unhealthful, unwholesome, or in any way unfit for human food shall be placed under seizure as provided by Revised Statute 40:632 of the State Food, Drug and Cosmetic Law. When final inspection is made, if the article is condemned it shall immediately be denatured or treated in such a manner as to render it unfit for food and removed to an incinerator, or to a cooker to be rendered into tankage, or buried, dependent on facilities available for its destruction. If, however, upon final inspection the article is passed for food, the inspector shall release the article and authorize its sale as food.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§966. Marking of Meat and Meat Products [Formerly 49:3.1701]

A. No meat or meat product shall be brought into any slaughter house, meat packing plant, sausage kitchen or other meat product plant unless it can be identified by marks, seals, brands, or labels, as having been slaughtered, prepared or packed in an establishment having a valid permit to operate issued by the department or such markings to show that it is a product of an establishment operating under federal or approved state, parish or municipal supervision, nor shall any meat market deal in meats or meat products other than as specified in these regulations. All meats and meat products in any meat market, meat product plant, sausage kitchen, meat packing plant, slaughter house, or any establishment where meats or meat products are held, shall be subject to reinspection in such manner and at such times as may be necessary to establish its fitness for food. If upon inspection any article of meat or meat product is found to be unsound, unhealthful, unwholesome, or otherwise unfit for food, the article shall be condemned and disposed of according to §965.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§967. Meat and Meat Products, Distribution in Commerce [Formerly 49:3.1702]

A. Any meat or meat product which bears the identifying permit number, stamp, tag, label or other markings as required by these regulations may be freely distributed in intrastate commerce, subject to such further restrictions as may be established by local ordinances, provided it is sound, healthful, wholesome and fit for human foods, and has not been processed, reprocessed or changed in any manner so as to alter the character of the product; and provided further, that it is registered with the department as a processed food if subject to the registration provisions of R.S. 40:627 and R.S. 40:628 of the State Food, Drug and Cosmetic Law.

B. The word "inspected" or any other word or phrase implying that the product has been inspected in a city, parish, state or federal supervised plant shall not appear on labels of meat or meat products unless produced in a plant operating under approved city, parish state or federal inspection service.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§968. Meat and Meat Products, Inspection [Formerly 49:3.1800]

A. All processes used in curing, pickling, rendering, canning or otherwise preparing any meat or meat product, shall be subject to inspection at all times during reasonable working hours by any authorized representative of the department. Fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans or containers of any kind, shall be clean and sanitary and shall be of such materials and construction as will not contaminate the meat or meat products. All steps in the process of manufacture shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§969. Wholesome of Ingredients [Formerly 49:3.1801]

A. All substances and ingredients used in the manufacture or preparation of any meat or meat product shall be clean, sound, healthful, wholesome and otherwise fit for human food.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§970. Chemical Preservatives and Dyes [Formerly 49:3.1900]

A. No meat or meat product shall contain any substance which impairs its wholesomeness, nor contain any dye, preservative, or added chemical except as permitted by §972.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§971. Approved Additives [Formerly 49:3.1901]

A. There may be added to meats or meat products, with proper declaration when allowed by these regulations, common salt, sugar (sucrose), refined corn sugar (dextrose), wood smoke, vinegar, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite and any other substance approved by the department.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§972. Artificial Coloring of Prepared Fats and Product Casings [Formerly 49:3.1902]

A. Harmless coloring matters only may be used in or on meat products, and these only with the approval of and in such manner as may be prescribed by the department. Such colorings may be used in the manner and under conditions as follows:

1. they may be added to prepared fats;

2. they may be used in the preparation of casings, or by dipping casing-covered meat products, or by other approved methods provided they do not penetrate the meat product contained in the casing;

3. They shall be declared as required under §915 and §954.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§973. Sausage Ingredients, Meat, Fish and Crayfish Components [Formerly 49:3.1903]

A. Except as otherwise provided by this regulation, prepared sausage or sausage meat shall be made from meat, or meat and meat by-products, fish or crayfish seasoned with condimental proportions of condimental substances. The term "sausage" shall be construed to include head cheese, liver pudding and blood pudding, fish sausage and crayfish sausage.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§974. Sausage Ingredients, Non-Meat Components [Formerly 49:3.1904]

A. Under appropriate label declaration, sausage may contain not more than 3.5 percent individually or collectively, of cereal, vegetable starch, starchy vegetable flour, dried milk, dried skim milk, soya flour, or any other fillers, extenders or binders approved by the department. For the purpose of facilitating grinding, chopping and mixing, not more than 10 percent of water or ice may be added to the sausage, unless otherwise prohibited by these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§975. Sausage Ingredients, Milk Components [Formerly 49:3.1905]

A. Milk, skimmed milk, dried milk, dried skim milk, malted milk, and analogous substances and products which may be approved for such purpose, may be added to sausage

provided their use does not result in added water or moisture in excess of the amount permitted in §974. Sausage shall not contain dried milk or any other milk or milk product in excess of 3.5 percent, and if cereal, vegetable starch or vegetable flour is also added, the combined amount of all such products shall not exceed 3.5 percent.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§976. Fats, Added Water
[Formerly 49:3.1906]

A. No rendered edible animal fat, or mixture of fats containing rendered edible animal fat other than oleomargarine and puff-pastry shortening, shall contain added water.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§977. Meat Products Ingredients, Special Permission Required
[Formerly 49:3.1907]

A. The use of substances necessary for the proper preparation, clarification, or refining of meats or meat products may be permitted, subject to approval by the department, provided they do not impair the quality of the meat or meat product and are eliminated during further processes of manufacture; as for example, the use of bicarbonate of soda and Fuller's earth in the preparation of fats, and the use of sal soda or lime in the cleansing of tripe.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§978. Canning
[Formerly 49:3.2000]

A. Any canned meat or meat product which requires sterilization to preserve it shall be sterilized in the can or container on the same day that the cans or other containers are filled. Defective or leaky cans discovered after the process of sterilization has been completed shall not be repaired or repacked, unless

1. the repairing or repacking be completed within six hours after the process of sterilization has been completed; or

2. if their defective or leaky condition be discovered during an afternoon run, they be held in coolers of a temperature not exceeding 34° F. until the following day, when they may be repaired or repacked. Repaired or repacked cans and containers shall be sterilized. Sterilization will be completed within the meaning of this paragraph when the cans, after cooking, have cooled sufficiently for inspection and handling. The contents of all defective or leaky cans not repaired or repacked in compliance with this paragraph shall be condemned and destroyed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§979. Sausage in Oil, Preparation Temperature and Time
[Formerly 49:3.2001]

A. Sausage prepared and packed in oil shall be heated to a temperature e of at least 160° F, and this temperature shall be maintained within the can for not less than 30 minutes. Cans should show good vacuum.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§980. Trichinae in Pork Prohibited
[Formerly 49:3.2002]

A. Inasmuch as it cannot certainly be determined, by any present known method of inspection, whether the muscle tissue of pork contains trichinae, and inasmuch as live trichinae are dangerous to health, no article of a kind prepared customarily to be eaten without cooking shall contain any muscle tissue of pork unless the pork has been subjected to a temperature sufficient to destroy all live trichinae, or such other treatment as may be prescribed by the department.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§981. Hermetically Sealed Containers, Coding
[Formerly 49:3.2100]

A. Each establishment operating to can any meat or meat product in hermetically sealed containers shall submit to and have approved by the department a code which shall appear legibly on each can or container. This code shall show the plant permit number, date and year packed, the product contained in the can and the batch number. Where only a day code is used, the entire day's output shall be considered as one batch. The permit number and date code must be embossed in the tin or cover.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§982. Approved Animal Casings
[Formerly 49:3.2200]

A. The only animal casings that may be used as containers for any meat or meat product as those of cattle, sheep, swine, or goats.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§983. Washing of Approved Animal Casing
[Formerly 49:3.2201]

A. Casings for meats or meat products shall be carefully washed and thoroughly flushed with clean water. Only those that are suitable for containers and are clean shall be used.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§984. Animal Casings, Infestation Prohibited
[Formerly 49:3.2202]

A. Portions of casings which show infestation with Aesophagostomum, or other nodule-producing parasites, and weasands infested with larvae of Hypoderma Lineatum, shall not be used.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§985. Animal Casings, Intestines
[Formerly 49:3.2203]

A. Intestines shall not be used as ingredients of meat food products, except as provided in these regulations for use as casings.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§986. Animal Casings, Processing
[Formerly 49:3.2204]

A. The fermenting and sliming of hog and sheep casings shall be done in compartments designated for this purpose only.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§987. Processing of Animal Heads
[Formerly 49:3.2300]

A. Heads for use in the preparation of meat food products shall be split and the bodies or the teeth, the turbinated and ethmoid bones, ear tubes and horn butts removed, and the heads thoroughly cleaned.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§988. Processing of Kidneys
[Formerly 49:3.2301]

A. Kidneys for use in the preparation of meat food products shall be first freely sectioned and then thorougly soaked and washed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§989. Cattle and Hog Stomachs, Processing of
[Formerly 49:3.2302]

A. Cattle paunches and hog stomachs for use in the preparation of meat food products shall be thoroughly cleaned on all surfaces and parts immediately after being emptied of their contents.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§990. Tonsils Prohibited in Meat Food Products
[Formerly 49:3.2303]

A. Tonsils shall be removed and shall not be used as an ingredient of any meat food products.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§991. Use of Blood
[Formerly 49:3.2400]

A. Blood which comes in contact with the surface of the body of any animal or is otherwise contaminated shall not be collected for food purposes. The defibrination of blood intended for food purposes shall not be performed with the hands.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§992. Sample Collection
[Formerly 49:3.2500]

A. Any representative of the department may at any reasonable time during working hours, collect for examination samples of any meat or meat products, water, dye, chemical, preservative, spice or other articles for use in

or on any meat or meat product at any place where such articles are pre pared, packed, stored or held for sale within the state.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§993. Non-Approved Dyes and Chemical Preservatives Prohibited in Permitted Establishments [Formerly 49:3.2600]

A. No dye, chemical, preservative, or other substance, the use of which is not permitted by these regulations, shall be brought into, kept, or used, in any establishment dealing in the preparation, manufacture, storage or sale of any meat or meat product.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§994. Compliance with State Food and Drug Laws Required [Formerly 49:3.2700]

A. All meats and meat food products shall comply in every respect with the provisions of Act 142 of 1936 as amended, (The Food, Drug and Cosmetic Law). Failure to comply renders all such articles sold or offered for sale liable to seizure for condemnation, and renders manufacturers and vendors amenable to prosecution under the Act.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§995. Horsemeat Labeling and Sale [Formerly 49:3.2800]

A. No person shall keep, have in his possession, display, or offer for sale any horsemeat in an establishment dealing in any other meat which is offered for sale for human consumption unless such horse meat is so packaged, denatured, and labeled as to preclude its use for human consumption.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§996. Horsemeat must be Properly Identified [Formerly 49:3.2801]

A. Any horsemeat offered or displayed for sale, either fresh, cured, smoked, salted, canned or otherwise prepared in a manner capable of being used as food for human consumption, shall be prominently and conspicuously labeled as horsemeat with any other descriptive labeling necessary to properly identify the product so offered or displayed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§997. Slaughter of Horses [Formerly 49:3.2900]

A. The slaughter of horses, and the preparation and handling of the meat and meat products thereof, shall be conducted entirely separate and apart from any establishment in which cattle, sheep, swine, or goats are slaughtered, or the meat or meat products thereof are prepared or handled.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§998. Horse Slaughter must be in Compliance with Regulations [Formerly 49:3.3000]

A. Any slaughter houses engaged in the slaughtering of horses, and any establishment in which carcasses, parts of carcasses, meat, meat products of or derived from horses, are wholly or in part, canned, cured, smoked, salted, packed, rendered, or otherwise prepared for transportation of sale in commerce and which are capable of being used as food for human consumption, shall be operated in compliance with all pertinent requirements of these regulations and of the regulations of the State Sanitary Code.

B. All horses, carcasses, parts of carcasses, meats and meat products thereof shall be conspicuously labeled, marked or branded "Horse Meat".

C. For the purpose of these regulations, the term "Horse Meat" shall mean and include meat from horses, donkeys or mules.

D. Only harmless green ink shall be used in branding horse meat and horse meat products with the mark of inspection.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

Chapter 11. Drug Regulations

§1101. Drug Name [Formerly 49:4.0010 Drug Name]

A. The name by which a drug is designated shall clearly distinguish and differentiate the drug from any name recognized in an official compendium unless the drug complies in identity with the identity prescribed in an official compendium under such recognized name.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1103. Drug Name Differing from Official Compendium [Formerly 49:4.0020]

A. A statement that a drug differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which the drug so differs, and the extent of each such difference.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1105. Misbranding, False or Misleading Representation [Formerly 49:4.0030]

A. A drug or device may be deemed misbranded if any representation in the labeling is false or misleading with respect to another drug or device, or a food or cosmetic.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1107. Misbranding, Name Suggest Only One Ingredient [Formerly 49:4.0040]

A. A drug may be deemed misbranded if it contains two or more ingredients and the designation of the drug in the labeling is by a name which includes or suggests the name of one or more but not of all the ingredients are stated elsewhere in the labeling.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1111. Misbranding Firm Name and Address on Label [Formerly 49:4.0050]

A. Where the name which appears on the label of any drug or device is not that of the manufacturer, the name shall be qualified by a phrase which reveals the connection such person has with the drug or device, such as "Manufactured for and Packed by ...," "Distributed by ...", "Retailed by ...", or other similar word or phrase which expresses the facts. Where the name of the actual manufacturer or packer does not appear on the label, this information as well as information as to the actual place where the drug or device is manufactured or packed shall be made known to the department on request.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1113. Misbranding, Name of the Place of Business [Formerly 49:4.0060]

A. Where a person manufactures, packs, sells, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business instead of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1115. Misbranding Prohibited [Formerly 49:4.0070]

A. The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be misleading in any particular.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1117. Quantity of Contents [Formerly 49:4.0080]

A. The statement of the quantity of the contents of a package of a drug shall reveal the quantity of the drug in the package, exclusive of wrappers and other material packed with the drug.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1119. Expression of Quantity of Contents [Formerly 49:4.0090]

A. The statement of the quantity of contents shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of the drug to express quantity thereof and which give accurate information as to the quantity. However, if no general usage in expressing accurate information as to the quantity of the drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampoule or other unit form shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of measure if the drug is liquid. The statement of the quantity of a drug which is in tablet, capsule, ampoule or other unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate

information as to the quantity of the drug in the package, by a statement (in such terms manner and form as are not misleading) of the weight or measure of the units, or of the quantity of each active ingredient in each unit, which will give accurate information to the consumer or user.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1121. Quantity of Contents, Devices [Formerly 49:4.0100]

A. The statement of the quantity of a device shall be expressed in terms of numerical count.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1123. Quantity of Contents, Terms Used [Formerly 49:4.0110]

A. A statement of the quantity of contents by weight shall be in terms of the avoirdupois pound, ounce and grain, or of the kilogram, gram and milligram. A statement of the quantity of contents by liquid measure shall be in terms of the United States Gallon of 231 cubic inches and of quart, pint, fluid ounce and fluid dram subdivision thereof, or of the liter, milliliter or cubic centimeter, and shall express the volume at 68 degrees Fahrenheit (20 degrees Centigrade).

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1125. Quantity of Contents, Use of Fractions [Formerly 49:4.0120]

A. Statements of the quantity of contents of a drug shall contain only those fractions that are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms, a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1127. Quantity of Contents, Use of Largest Units [Formerly 49:4.0130]

A. Except as provided for in paragraph §1129, a statement of the quantity of a drug in the terms of weight or measure applicable to such drug under the provisions of §1119 shall express the number of the largest unit specified in §1123 which is contained in the package. For example: the statement on the label of a package which contains one pint of a drug shall be "1 pint" and not "16 fluid ounces". Where the number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units if any smaller unit is specified in §1123. For example: "1 1/4 pounds" may be expressed as "1 pound 4 ounces". The stated number of any unit smaller than the largest unit (as specified in §1123) contained in the package shall not equal or exceed the number of these smaller units which are contained in the next larger unit so specified. For example: instead of "1 quart 16 fluid ounces", the statement shall be "1 1/2 quarts", or "1 quart 1 pint".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1129. Quantity of Contents, Customary Usage [Formerly 49:4.0140]

A. In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package; or as units smaller than the largest unit contained therein; the statement may be made in accordance with such custom if it is informative to consumers.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1131. Quantity of Contents, Minimum Quantity [Formerly 49:4.0150]

A. The statement of the quantity of the contents of the package of a drug or device shall express the minimum quantity, or the average quantity. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to mean the average quantity, except when the drug is in ampoules. When in ampoules, the statement of the quantity of the contents of a drug shall be considered to express the minimum quantity.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1133. Quantity of Contents, Variation from Minimum Quantity [Formerly 49:4.0160]

A. Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after the drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be

unreasonably large. In the case of a liquid drug in ampoules the variation above the stated measure shall comply with the excess volume prescribed by any official compendium for filling of ampoules.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1135. Quantity of Contents, Where Minimum Quantity Not Expressed [Formerly 49:4.0170]

A. Where the statement does not express the minimum quantity, variations shall be permitted:

1. when caused by ordinary and customary exposure, after the drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

2. when caused by unavoidable deviations in weighing, measuring or counting the contents of individual packages, which occur in good packing practices. However, under this provision variations shall not be permitted to such an extent that the average of the quantities in the package comprising a shipment or other delivery of the drug or device is below the quantity stated; and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1137. Quantity of Contents, Variations [Formerly 49:4.0180]

A. The extent of variations from the stated quantity of the contents permissible under §1133 and §1135 shall be determined by the facts in the case of each shipment or other delivery.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1141. Quantity of Contents, Statements, Exemptions [Formerly 49:4.0190]

A. The label of a drug or device shall be exempt from compliance with the requirements of R.S. 40:617 (A) (3) (b) if:

1. the statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of §1117, §1119 and §1121, together with all other words, statements and information required by or under authority of the Act to appear on the label of such drug or device cannot, because of insufficient area for larger label space, be placed on the labels so as to comply with the requirements of R.S. 40:617 (A) (3) and regulations promulgated thereunder; or

2. the quantity of the contents of the package, as expressed in terms of numerical count in compliance with §1119 or §1121 is less than six units, and the units can be easily counted without opening the package.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1143. Misbranding, Prominence and Conspicuousness of Words [Formerly 49:4.0200]

A. A word, statement or other information required by or under authority of the Act to appear on the label shall be deemed to lack that prominence and conspicuousness required by 617(A)(4) of the Act by reason (among other reasons) if:

1. the failure of such word, statement or information to appear on the part or panel or the label which is presented or displayed under customary conditions of purchase; or

2. the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions or purchases, the part or panel displayed; or

3. the failure of the label to extend over the area of the container or package available for extension of the label so as to provide sufficient label space for the prominent placing of such word;

4. insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space for any word, statement, design or device which is not required by or under authority of the Act to appear on the label; or

5. insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design or device; or

6. smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1145. Labeling Exemptions Prohibited [Formerly 49:4.0210]

A. No exemption depending on insufficiency of label space, as prescribed in relations §1141 and §1185

promulgated under R.S. 40:617 (A) (3), (6) and (7) shall apply if such insufficiency is caused by:

1. the use of label space for any word statement, design or device which is not required by or under authority of the Act or these regulations to appear on the label; or

2. the use of label space to give greater conspicuousness to any word, statement or other information than is required by 617(A)(3) of the Act; or

3. the use of label space for any representation in a foreign language.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1147. English Language Required [Formerly 49:4.0220]

A. All words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1149. Foreign Language Labeling [Formerly 49:4.0230]

A. If the label or labeling contains any re presentation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the foreign language.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1151. Official Names Required [Formerly 49:4.0240]

A. The name of a substance or derivative required to be borne on the label of a drug by regulation §1163 or R.S. 40:617 (A) (5) and regulations promulgated thereunder shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation corn plies with the provisions of R.S. 40:617 (A) (4).

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1153. Names of Narcotic and Hypnotic Substances [Formerly 49:4.0250]

A. A statement on the label of a drug listing as an ingredient a product which is a chemical derivative of a substance named in R.S. 40:617 (A) (5), shall show the name of the substance from which the ingredient is derived and shall state that the ingredient is a derivative thereof.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1153. Habit Forming Drugs [Formerly 49:4.0260]

A. Each of the following chemical derivatives of a substance named in R.S. 40:617(A)(5) is hereby designated as habit forming. (Please refer to the following table)

Parent Substance Description	Chemical Derivative	Chemical Description of Derivative
Barbituric Acid	Alurate	(5-allyl-5-isopropyl-barbi-turic acid)
	Amytal	(5 ethyl 5 isoamyl-barituric acid.)
	Barbital	(5, 5 diethyl barbituric acid)
	Butisol	(5-ethyl 5-sec-butyl-bar-bituric acid)
	Cyclopal, Cyclopen	(5-allyl-5-cyclopanteyl-barituri c acid)
	Delvinal	(5-ethy1-5- (5-ethyl-l-butenyl)-barbituric acid)
	Dial	(5, 5-diallyl-barbituric acid)
	Eldoral	(5-ethy1-5-(1-piperidy1)-barbituric acid)
	Eunacron	(5-(2-bromoally1)-5-isopropyl-1-methyl-barbituric acid)
	Evipal	(l,5-dimethyl-5-(l-cyclohexenyl)-barbituric acid)
	Ipral	(5-ethyl-5-isopropyl-barituric acid)
	Mebaral	(5-ethy1-5-pheny1-1-methyl-barbituric acid)
	Nacronumal	(5-ally1-5-isopropy1-1-methyl-barbituric acid)
	Neonal	(5-ethyl-5-butyl-bar-bituric acid)
	Nostal	(5-isopropyl-5-(2-bro-moally1)-barbituric acid)
	Ortal	(5-ethyl-5-hexyl-barbituric acid)
	Pentenal	(5-ethy1-5-cyclopentenyl-barbituric acid)
	Pentobarbital	(5-ethy1-5-(1-methyl-buty1)-barbituric acid)
	Pentothal	(5-ethy1-5-(1-methyl-buty1)-2-

		thio-barbituric acid)
	Pernoston	(5-sec-buty1-5-(2-bro-moally1)-barbituric acid)
	Phanodorn	(5-ethy1-5-(1-cyclohex-eny1)-barbituric acid)
	Phenobarbital	(5-ethyl-5-phenyl-barbi-turic acid)
	Proponal	(5,5-dipropyl-barbituric acid)
	Rutonal	(5-methyl-5-phenyl-bar-bituric acid)
	Sandoptal	(5-ally1-5-isobutyl-bar-bituric acid)
	Sigmodal, Rectidon	(5-(2-bromoally1)-5-(1-methylbuty1)-barbituric acid)
	All lithium, sodium potassium, magnesium calcium, strontium, ammonium salts of the foregoing chemical derivatives of barbituric acid.	
	Seconal	(sodium-5-ally1-5-(1-methylbuty1)-barbiturate)
	All salts of the foregoing chemical derivative formed by replacing the sodium with lithium, potassium, magnesium, calcium, strontium, or ammonium radical.	
Bromal	Bromal Hydrate	(tribromoacetaldehyde hydrate)
	Brometone	(2-(tribromomethy1)-2-propanol)
	Bromoform	(tribromomethane)
Cannabis marijuana	Extract of Cannabis, Fluid extract of Cannabis	
	Tincture of Cannabis	
Carbromal	Acetylcarbromal	(a-bromo-a-ethyl-butyrylacetyl-urea) (a-bromoisovaleryl-urea)
	Neuronal	(a-bromo-a,a-diethyl-acetamide)
Chloral	Sedormid	(a-allylisovaleryl-urea)
	Alpha-Chloralose	(a-(B-trichloro-a-hydroxy-ethy1)- d-glucoside)
	Chloralformamide	(N-(B-trichloro-a hydroxy-ethy1)-formamide)
	Chloral Hydrate	(trichloroacetaldehyde hydrate)
	Chloralimide	(trichloroethyl-ideneimine)
	Chlorobutanol	(2-(trichlormethy1)-2-propanol)
Cocaine	All salts of cocaine obtained by combining cocaine with any acid.	
Codeine	Dicodid	(dihydro-codeinone)
	Eucodal	(dihydrohydroxy-co-deione)
	All salts of the foregoing chemical derivative of codeine, and all salts of codeine obtained by combining any such derivative or codeine with any acid.	
	Eucodin	(codeine methyl bromide)
Heroin	All salts of heroin obtained by combining heroin with any acid.	
Isonipecaine	Demerol	
Morphine	Dilaudid	(dihydro-morphine)
	Ethylmorphine	
	Paramorphan	(dihydro-morphine)
	All salts of the foregoing chemical derivatives of morphine, and all salts or morphine, obtained by combining any such derivative or morphine with any acid.	
Opium	Extract of Opium	
	Fluid extract of Opium	
	Tincture of Opium	
Paraldehyde	Metaldehyde	
Sulphonmethane	Sulfonethy-methane	(2, 2-diethylsufonyl-butane)
	Sulfonthyl-methane methane	(3, 3-diethylsufonyl-pentane)

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1155. Quantity Expression, Unit Form [Formerly 49:4.0270]

A. If the drug is in tablet, capsule, ampoule or other unit form, the statement of the quantity or proportion of the substance or derivative contained therein shall express the weight or measure of the substance or derivative in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of the substance or derivative in a specified unit of weight or measure of the drug. The statement shall be in terms which are informative to the ordinary consumer and user of the drug.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1157. Habit Forming Drugs, Labeling and Warning Statement
[Formerly 49:4.0280]

A. The names and quantities or proportions of all such substances and derivatives, and the statement: "Warning—May Be Habit Forming", shall immediately precede or immediately follow (without intervening written, printed or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1159. Habit Forming Drugs, Prescription Required Department
[Formerly 49:4.029]

A. Drugs designated by the Louisiana department as habit forming or dangerous, shall only be sold or dispensed on the original prescription of a physician, dentist or veterinarian. The refilling of such a prescription for any habit forming or dangerous drug, except upon authorization of the original prescriber, is hereby prohibited. Any drug, the label of which bears the caution legend sold or dispensed on the prescription of a physician, dentist or veterinarian and such prescription shall not be refilled except upon the authorization of the original prescriber. For the purpose of these regulations a prescription is hereby defined as: A written direction for the preparation and administration of a drug, signed by a legally authorized physician, dentist or veterinarian.

B. It shall be a violation of these regulations for any person other than a duly authorized physician, dentist or veterinarian, to prepare, issue, or offer to any other person a written direction for the preparation and administration of a dangerous or habit forming drug or any drug, the label of which bears the caution legend that such drug is to be sold only on a prescription.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1161. Habit Forming Drugs, Labeling Exemptions
[Formerly 49:4.0300]

A. A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement "Warning—May Be Habit Forming—"

1. If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

2. If the only substance or derivative subject to R.S. 40:617 (A)(5) contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

3. If the only substance or derivative subject to R.S. 40:617 (A)(5) contained in such drug is chlorobutanol, which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1163. Misbranding, Ingredients Designation
[Formerly 49:4.0310]

A. A drug shall be deemed to be misbranded if it is not designated solely by a name recognized in an official compendium, unless its label bears:

1. the common or usual name of the drug, if such there be; and

2. in case it is made from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind and proportion of any alcohol, ana also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanth in, strychnine, thyroid, or any derivative or preparation of any such substances contained therein: Provided, that to the extent that compliance with the requirements of Paragraph 2 of this Subsection is impracticable, exemptions shall be as provided by §1186.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1165. Prescription Drugs List
[Formerly 49:4.0320]

A. The following drugs in therapeutically effective proportions are considered dangerous for use otherwise than on the prescription of a duly qualified physician, dentist, or veterinarian licensed by law to administer drugs:

1. Acetanilid (where dosage provides a total daily intake of more than 5 grains or more than 2 1/2 grains during any 3 hour period);

2. Acetophenetidln (where daily dosage provides more than 15 grains);

3. Aconite (for internal use);

4. Aminopyrine;

5. Antipyrine (where daily dosage provides more than 15 grains);

6. Barbiturate;

7. Benzedrine sulphate (for internal use);

8. Bromides (where dosage involves consumption of more than 30 grains per day or more than 15 grains during any 3 hour period;

9. Bromide—Acetanilid combinations (where dosage provides more than a total daily dose of 15 grains of sodium bromide and 5 grains of acetanilid or more than 7 1/2 grains of sodium bromide and 2 1/2 grains of acetanilid during any 3 hour period. Comparable amounts of other bromide preparations are subject to the same restrictions);

10. Cantharides (for internal use);

11. Causaline Sedormide;

12. Chrysarobin or goa powder

13. Chrysophanic acid;

14. Cincophen, Neocincopene and other cincophen derivatives;

15. Colchicine;

16. Colchicum;

17. Digitalis;

18. Emetine;

19. Epinephrine (in solution of 1 percent or stronger);

20. Ipecac (in daily dosage greater than 10 grains)

21. Phosphides;

22. Phosphorus;

23. Radium and radio—active drugs;

24. Squill;

25. Strophanthus;

26. Strychnine (in daily dosage greater than 1/20 grain);

27. Sulfanilamide;

28. Sulfapyradine and other related "sulfa" drugs;

29. Sulfathiazole (for internal use);

30. Tansy, Tansy Oil;

31. Thiocyanates;

32. Thyroid;

33. the "anthelmintic" drugs:

a. carbon tetrachloride;

b. tetrachlorethylene;

c. male fern (aspidium);

d. santonin;

e. wormseed oil (chenopodiurn oil);

f. thymol.

B. Where the legend: "Caution—to be used only by or on the prescription of a Physician (Dentist, or Veterinarian)" appears on a packaged drug instead of directions for use, the retailer shall observe the injunction that the article be dispensed only upon prescription.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1167. Dispense Defined
[Formerly 49:4.0330]

A. The term "dispense" as used in 4.0701 shall mean the use of a drug as an ingredient in the corn pounding of any prescription issued by a physician, dentist, or veterinarian in his professional practice.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1169. Physician, Dentist and Veterinarian, Must be Licensed
[Formerly 49:4.0340]

A. The terms "physician", "dentist", and "veterinarian", as used in relation to the exemption from any labeling requirement of any drug or device shall include only those physicians, dentists or veterinarians who are licensed by law to administer or apply such drug or device.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1171. Specific Names Required
[Formerly 49:4.0350]

A. The name of an ingredient, substance, derivative, or preparation required by §1163 to be borne on the label of a drug shall be the name thereof which is listed in §1163, or if not so listed, shall be a specific name and not a collective name. Where an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth for such an article in the compendium, the ingredient may be designated on the label of the drug by the common or usual name in the compendium.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1173. Quantities Required
[Formerly 49:4.0360]

A. Where a component of a drug contains a substance the quantity or proportion of which is required by §1163.A.2 to appear on the label and the component is not a derivative

or preparation of that substance, as defined in §1171, the label shall bear in conjunction with the name of the component, a statement of the quantity or proportion in the drug of the substance required by §1163.A.2 to appear on the label.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1175. Abbreviations and Chemical Formulas, Not Common or Usual Names [Formerly 49:4.0370]

A. An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidin"; "amino pyrine" the same as "amidopyrine". The name "alcohol", without qualification shall mean "ethyl alcohol".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1177. Misbranding, Ingredients, Derivatives Designation [Formerly 49:4.0380]

A. A derivative or preparation of a substance named in §1163.A.2 is an article which is derived or prepared from such substance by any method.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1179. Misbranding, Ingredients, or Derivatives [Formerly 49:4.0390]

A. A statement on the label of a drug or the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named §1163.A.2, shall show the substance from which the ingredient is derived or prepared and shall also show that the ingredient is a derivative or preparation thereof.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1181. Labeling, Weight or Measure of a Drug [Formerly 49:4.0400]

A. If the drug is in tablet, capsule, ampoule, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of the substance, derivative or preparation in each unit. If the drug is not in unit form, the statement shall express the weight or measure of the substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the proportion in the drug. Such a statement shall be in terms which are informative to the ordinary consumer and user of the drug.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1182. Alcohol and Other Ingredient Labeling [Formerly 49:4.0410]

A. A statement of the proportion of alcohol present shall express the percentage of absolute alcohol by volume at 60 degrees Fahrenheit (15.56 degrees Centigrade). A statement of the proportion present of any substance, derivative, or preparation other than alcohol shall express the proportion by weight, except that, if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the proportion present by volume at 68 degrees Fahrenheit (20 degrees Centigrade), but in such case the statement shall be so qualified as to show definitely that the proportion is expressed by volume.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1183. Statement of Quantity or Proportion of a Derivative or Preparation [Formerly 49:4.0420]

A. In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative to consumers or users of the drug regarding the activity or consequence of use thereof as would be a statement of the quantity or proportion of the substance from which the derivative or preparation is derived or prepared, than the quantity or proportion of such substance shall also be stated on the label of the drug.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1184. Misleading Labeling [Formerly 49:4.0430]

A. A label of a drug may be deemed to be misleading by reason (among other reasons) if:

1. The order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given the names; or

2. Its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such a proportion or other fact is material in the light of the representation that the ingredient, substance, derivative, or preparation is a constituent of the drug.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1185. Labeling—Exemption from Requirements, Conditions or Exemption [Formerly 49:4.0440]

A. The label of a drug shall be exempt from compliance with the requirements of §1163.A.2 if the container is so small that the label when extended over the area available for label space is of insufficient size so that all words, statements, and other information required by or under authority of the Act to appear on the label of such drug, cannot be so placed on the label as to comply with the requirements of R.S. 40:617 (A)(4) and regulations §1143 and its subparagraphs promulgated thereunder. This exemption shall be on the condition that if the statement on the label of the quantity of the contents is omitted as authorized by §1141 under R.S. 40:617 (A)(3) and this omission will allow sufficient space to include the information required by §1163.A.2 even though the statement is not so conspicuous as to render it likely to be read by the ordinary individual under customary conditions of purchase, then the statement of the quantity of contents shall be omitted and the information required by 4.07 (2) shall be stated as prominently as is practicable.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1186. Labeling—Exempting of Certain [Formerly 49:4.0450]

A. A drug shall be exempt from the requirements of §1163.A.2 with respect to the alkaloids, atropine, hyoscine or hyoscyamine, contained in the drug, if the alkaloid is contained therein as constituent of belladonna, hyoscyamus, scopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of the drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in the ingredient. This exemption shall be on the condition that the label of the drug shall state the quantity or proportion of total alkaloids contained therein as constituents of the ingredient.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1187. Drug Labeling—Directions, Warnings [Formerly 49:4.0460]

A. The labeling of drugs or devices shall bear:

1. adequate directions for use; and

2. adequate warnings against misuse in connection with pathological conditions or by children where its use may be dangerous to health; or against unsafe dosage, methods, or duration of administration or application, in such manner and form as are necessary for the protection of users.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1188. Labeling—Inadequate Directions [Formerly 49:4.0470]

A. Directions for use may be deemed to be inadequate by reason, (among other reasons) of omission in whole or in part, or incorrect specification of:

1. directions for use in all conditions for which the drug or device is prescribed, recommended, or suggested in its labeling, or in advertising regarding it which is disseminated or sponsored by, or on behalf of, its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used; or

2. quantity of dose (including quantities for persons of different ages and different physical conditions); or

3. frequency and duration of administration or application; or

4. time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor); or

5. route or method of administration or application; or

6. preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1189. Labeling of Drugs or Devices—Exemptions from Requirements [Formerly 49:4.0480]

A. A shipment or other delivery of a drug or device shall be exempt from the requirements of §1187.A.1, if it complies with all of the following conditions.

1. Such drug or device, because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use or the collateral measures necessary to its use, is generally recognized by experts qualified by scientific training and experience to evaluate its safety and efficacy, as not safe and not efficacious for use except by or under the supervision of a physician, dentist, or veterinarian.

2. Such shipment or delivery is made for the purpose of exclusive use:

a. by physicians, dentists, or veterinarians in their professional practice; or

b. upon their prescriptions and under labeling bearing the directions for use specified in such prescriptions; or

c. in the manufacture of another drug or device.

3. Adequate directions for the use of such drug or device by physicians, dentists, or veterinarians, as the case may be, are readily available.

4. The label of such drug or device (other than surgical instruments and other devices to be used exclusively by physicians, dentists, or veterinarians in their professional practice) bears the statements: "Caution—To be dispensed only by a ..", the blank being filled in with one or more of the words "physician", "dentist", and "veterinarian", as the case may be.

5. No representation with respect to the conditions for which a drug or device is to be used and no statement of dosage or other direction for use appears in its labeling except representations or directions:

a. in printed matter supplied to a physician, dentist or veterinarian separately from such drug or device; and

b. specified in the prescription of a physician, dentist, or veterinarian upon which such drug or device was dispensed.

6. In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears a statement of the quantity or proportion of each active ingredient.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1190. Labeling Exemptions [Formerly 49:4.0490 Labeling Exemptions]

A. A shipment or other delivery of a drug or device shall also be exempt from the requirements of §1187.A.1 if it complies with all the conditions set forth in paragraph §1189.A.3 and §1189.A.6, and if such shipment or delivery is made to a physician, dentist, veterinarian, hospital, or clinic for the purpose of exclusive use by physicians, dentists, or veterinarians in their professional practice.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1191. Labeling Exemptions, for Manufacturing Use Only [Formerly 49:4.0500]

A. A shipment or other delivery of a drug or device shall also be exempt from the requirements of §1187.A.1, if it is made to a dealer or manufacturer for the purpose of exclusive use in the manufacture of another drug or device and its label bears the statement: For manufacturing use only".

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1192. Labeling Exemptions [Formerly 49:4.0510]

A. A shipment or other delivery of a drug or device shall also be exempt from the requirements of §1187.A.1 with respect to common uses, adequate directions for which are known by the ordinary individual.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1193. Labeling Exemptions Void [Formerly 49:4.0520]

A. No exemption under any provision of these regulations shall apply to any shipment or other delivery of:

1. a drug if the advertising disseminated or sponsored by or on behalf of its manufacturer, packer, or other person responsible for making such shipment or delivery, contains any representation not borne by its labeling;

2. a drug intended for administration by iontophoresis or by injection into or through the skin or mucous membrane;

3. a drug or device if such shipment or delivery is made in the course of the conduct of a business or dispensing drugs or devices by mail order or dispensed pursuant to diagnosis by mail.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1194. Expiration of Labeling Exemption [Formerly 49:4.0530]

A. Any exemption of a drug or device under §1189, §1190, or §1191 immediately expire if the drug or device, or any part thereof, is disposed of for any purpose other than the exclusive use specified. Any person responsible for such an expiration of exemption shall be considered as having caused an act of misbranding for which such person shall be liable, unless, prior to such disposition, the drug or device is relabeled to comply with the requirements of §1187.A.1 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1195. Labeling Exemption, Drugs to be Processed, Labeled or Repackaed [Formerly 49:4.0540]

A. A drug or device which is to be processed, labeled or repacked, in substantial quantities in accordance with regular trade practice, at an establishment other than were originally processed or packed, shall be exempt, except as provided by §1196 and §1197, from compliance with the labeling and packaging requirements of R.S. 40:616 (5) R.S. 40:617 (A) (3), (5), (6) and (7) and §1187 of these regulations, during transit from the original establishment to the labeling, processing, or repacking plant, and the time of holding in such establishment if:

1. the person responsible for the transit of the drug or device in commerce is the operator of the establishment where the drug or device is to be processed, labeled or repacked; or

2. in case such person is not the operator, the shipment or delivery of the drug or device is made under a written agreement, signed by and containing the post office addresses of the person responsible for the shipment or delivery and the operator of the processing, labeling or repacking plant, and also containing specifications for the processing, labeling, or repacking, as the case may be, of the drug or device, which if followed will ensure that the drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of the processing, labeling, or repacking. Each party to the agreement shall keep a copy of the agreement until all the shipment or delivery subject to its terms have been removed from the processing, labeling, or repacking plant; and provided that copies of the agreement shall be made available for inspection at any reasonable hour by any officer or agent of the department who requests them.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1196. Voiding of Exemption under Clause [Formerly 49:4.0550]

A. Any exemption of a drug or device under §1195.A.1 shall immediately become void if the drug or device, or any part thereof, at time of removal from the original establishment is adulterated or misbranded within the meaning of the Act when so removed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1197. Voiding of Exemption Under Clause (2) of 4.0540 [Formerly 49:4.0560]

A. Any exemption of a drug or device under §1195.A.2 shall immediately become void:

1. Upon refusal by the person responsible for the shipment or delivery of the drug or device to make available for inspection a copy of the agreement specified in, and required §1195.A.2.

2. Upon refusal by the operator of the establishment where the drug or device is to be labeled, processed, or repacked to make available for inspection a copy of the agreement specified in, and required by §1195.A.2.

3. If the drug or device, or any part thereof, at time of removal from the original establishment is adulterated or misbranded within the meaning of the Act when so removed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

§1198. Harmless Animal or Vegetable Dyes, Coal-Tar Colors, Use of [Formerly 49:4.057]

A. Only harmless animal or vegetable dyes and such coal-tar colors as have been certified by the Federal Food, Drug and Cosmetic Act of 1938 and defined under coal-tar color regulations as published by the Federal Security Agency in Service and Regulatory Announcements FDC 3, issued September, 1940, or as amended from time to time, shall be used in, offered for sale for use in, or distributed for use for purposes of coloring only in drugs, drug products, drug ingredients or their containers.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968.

Chapter 12. Seafood Regulations

Subchapter A. Shellfish Depuration Regulations

§1200. Definitions [Formerly 49:6.1000]

Depuration—a controlled process whereby shellfish harvested from restricted or approved waters are held live for purification in specially designed tanks for the primary purpose of reducing the number of pathogenic organisms that may be present to levels that are considered acceptable for human consumption without further thermal processing.

On Shore Wet Storage—a controlled process whereby shellfish harvested from waters approved by the state health officer for direct market harvesting are held live in specially designed tanks primarily for the purpose of desanding and/or improving palatability by increasing salt content.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR16:414 (May 1990).

§1201. Permit Requirements [Formerly 49:6.1010]

A. The controlled depuration of shellfish (oysters, clams, and mussels) is prohibited, unless the operator of the establishment has an unsuspended or unrevoked permit-to-operate issued by the Department of Health and Human Resources. Upon receipt of an application for a permit-to-operate, and successful completion of process verification studies, an inspection will be made by a duly authorized representative of the state health officer, and if the establishment is found properly equipped, in accordance with regulations, a permit will be issued authorizing the owner or operator of said establishment to engage in the business of operating either an on shore wet storage plant or depurating plant. Plans and specifications shall be submitted for review and approval prior to the construction of either type of plant.

1. Such permit may be suspended or revoked at any time for violation of these regulations. A suspended or revoked permit may be reinstated or re-issued when the proper improvements have been made.

B. The depuration plant owner shall designate a plant supervisor and assistant plant supervisor to be accountable for compliance with all applicable state laws and regulations.

C. The plant shall be used for no purpose other than the treatment or wet storage of shellfish and research activities related thereto. Persons not employed by the plant or representing the Department of Health and Hospitals, the Department of Wildlife and Fisheries, or the U.S. Food and Drug Administration shall not be allowed access to the plant or the laboratory except by permission of the plant supervisor or assistant plant supervisor.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1203. Tank Design and Construction [Formerly 49:6.1020]

A. The tank(s) shall be designed to allow for the uniform flow of sea water with no turbulence where shellfish are located. The tank(s) shall be of sufficient size to allow at least 8 cubic feet of sea water per bushel of shellfish in the tank(s). If the tank(s) is (are) rectangular in shape, length to width ratios shall be from 2:1 to 4:1. The maximum depth of tank(s) shall be 48 inches. The flow rate in the tank(s) shall be 1gpm/bushel.

B. Tanks shall be designed so that scum and sludge (shellfish feces and pseudo-feces, sand, grit, etc.) can be easily removed or flushed out. The bottom shall be sloped longitudinally at least 1/4 to 1/2 inch per foot toward the outlet end.

C. To facilitate proper cleaning and sanitation, as well a proper treatment of shellfish, tanks shall be constructed from impervious, non-toxic and inert materials. Coatings, when used, may include epoxy resins, powdered polyesters, vinyl bituminous water-tank paint, and paraffin. The coatings are not only for waterproofing but should provide a smooth, hard, non-porous surface for cleanability.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), repromulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1205. Plant Sanitation [Formerly 49:6.1030]

A. The general sanitation requirement of the plant, physical structure, equipment and utensils, and the sanitary requirements for operations, processes, and personnel shall follow the regulations issued under the Federal Food, Drug, and Cosmetic Act: "Human Food; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Molding," 21 CFR, Part 128, issued May 1969, and where applicable the sanitation requirements given in the latest edition of Part II of the National Shellfish Sanitation Program Manual of Operations, and Chapter IX, Louisiana State Sanitary Code, as revised March 20, 1984.

B. Material. Equipment surfaces that come into direct contact with the shellfish shall be made of smooth, corrosion-resistant, impervious, non-toxic materials which will not readily disintegrate or crack; and shall be so constructed as to be readily cleaned, and shall be kept in good repair.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1207. Plumbing and Related Facilities [Formerly 49:6.1040]

A. Plumbing shall be installed in compliance with state and local plumbing ordinances. Lavatories shall have running hot and cold water through a common mixer valve and shall be so located that their use by plant personnel can be readily observed. Signs shall be so located that their use by plant personnel can be readily observed.

B. Pump volutes and impellers shall be of a material which is non-toxic.

C. Plant domestic sewage shall be discharged into a sewage disposal system constructed in accordance with state and local requirements.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the

Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1209. Floors
[Formerly 49:6:1050]

A. Floors of rooms in which shellfish are handled or stored shall be constructed of concrete or other material impervious to water, shall be graded to drain quickly; shall be free from cracks and uneven surfaces that interfere with proper cleaning or drainage; and shall be maintained in good repair.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), repromulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1211. Lighting
[Formerly 49:6.1060]

A. To insure constant conditions for the shellfish undergoing the treatment process, a minimum of 10 foot-candles of illumination shall be provided at the water surface level inside the depuration tanks. The water surfaces shall not be subjected to the variations of direct sunlight.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), repromulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1213. Heating and Ventilation
[Formerly 49.6.1070]

A. Working rooms shall be heated and ventilated.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), repromulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1215. Water Supply
[Formerly 49:6.1080]

A. The water supply for depuration and wet storage uses shall be from a source approved by the Department of Health and Hospitals. When sea water is used in depuration or wet storage process it must be obtained from a body of water currently approved for that purpose by the Department of Health and Hospitals. For depuration purposes water may be recirculated through the tanks, but shall be discarded at the conclusion of the 48-hour treatment process. When wet storage is practiced, the sea water may be recirculated for a maximum of seven days before being discarded. The 48-hour and seven day discarding requirements may be waived when the depuration or wet storage facility utilizes a process approved by the Department of health and Hospitals for removing metabolic impurities from the process water.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1217. Rodent Control
[Formerly 49.6.1090]

A. The depuration plant shall be free from rodents, vermin, and domestic animals.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), repromulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1219. General Cleanliness
[Formerly 49:6.1100]

A. The plant shall be kept clean and free of litter and rubbish. Miscellaneous and unused equipment and articles which are not necessary to plant operations shall not be stored in rooms used for depuration or wet storage. Culled shellstock shall be removed promptly from the plant.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1221. Health of Personnel
[Formerly 49:6.1110]

A. Any person known to be infected with any disease in a communicable form shall be excluded from handling shellfish in the plant pending appropriate treatment and return to health.

AUTHORITY NOTE:Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), repromulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1223. Depuration—Laboratory Procedures
[Formerly 49:6.1120]

A. All shellfish and water sample shall be analyzed in a laboratory certified by the Department of Health and Hospitals. The laboratory shall be evaluated for compliance with the minimum requirements of the National Shellfish Sanitation Program, and American Public Health Association. The laboratory shall be supervised and operated by a person or persons approved in writing by the Department of Health and Hospitals.

B. The laboratory shall conduct routine bacterial examinations of process water and shellfish, and special examinations when necessary or required.

C. Bacterial examinations of shellfish and seawater shall be made in accordance with the most recent addition of "The Recommended Procedures for Bacterial Examination of Sea Water and Shellfish", 4th edition/1970 of the American Public Health Association, or other methods approved by the Department of Health and Human Resources.

D. All other physical, chemical, or biological tests shall be conducted according to the "Standard Methods for the Examination or Water and Waste Water", 15th edition/1980 prepared and published by American Public Health Association, the American Water Works Association, and the Water Pollution Control Federation, or other methods approved by the Department of Health and Human Resources.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1225. Depuration—Plant Operation [Formerly 49:6.1130]

A. Source of Shellfish. Shellfish shall be accepted for treatment at a shellfish depuration plant only from areas approved for this purpose by the Department of Health and Hospitals. A detailed description of all areas from which shellfish may be taken for depuration or wet storage, updated as necessary, shall be maintained by the Department of Health and Hospitals.

B. Shellfish Containers. Shellfish shall be accepted for treatment and released after treatment or wet storage in clean containers only.

C. Culling. All untreated shellfish upon arrival at the plant, shall be thoroughly inspected and culled by the plant supervisor or assistant plant supervisor. All dead shellfish, or shellfish in broken or cracked shells shall be destroyed.

D. Washing Shellfish. Before treatment, all shellfish shall be thoroughly washed or hosed with water taken from a source approved by the Department of Health and Hospitals. After treatment, all shellfish shall be thoroughly washed again with water taken from a source approved by the Department or Health and Hospitals.

E. Baskets Used in Treatment Process. All baskets used in the treatment process shall be of suitable size, designed for easy handling, and made of impervious material(s). Baskets shall be designed to allow water to flow freely over the shellfish in the treatment tanks. Baskets shall not be filled beyond the level which will allow free circulation of water during the treatment process. The height of the shellfish in the baskets shall not exceed 3 inches. Baskets shall be stacked in such a manner as to allow free circulation of water. Containers used for treatment or wet storage purposes shall not be used for any other purpose and no other equipment shall be stored in the treatment tanks.

F. Shellfish Treatment. All shellfish, upon receipt at the depuration or wet storage plant, shall be promptly treated or placed in controlled storage. Shellfish undergoing depuration shall be treated for a minimum period of 48 hours or for such time as authorized by the Department of Health and Hospitals. There shall be no predetermined time limits imposed upon shell fish held in wet storage.

G. Washing Treatment Tanks. After undergoing 24 hours of depuration, the shellfish shall be removed from the tanks and hosed down thoroughly with water from a supply approved by the Department of Health and Hospitals. The empty depuration tanks shall then be flushed with potable water to remove all filth and waste matter. The depuration tanks shall be sanitized with an approved sanitizing agent prior to being refilled with shellfish and treated sea water. When wet storage is practiced the tanks shall be drained, flush, and sanitized a minimum of once every seven days.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1227. Depuration—Shellfish Sampling Procedures [Formerly 49:6.1140]

A. Start Up Phase. Prior to certification of a depuration plant, the following minimum sampling schedule shall be followed in order to verify the effectiveness of the treatment process:

1. One or more shellfish samples (12 or more shellfish per sample) shall be collected for bacterial examination before the shellfish are submitted to the treatment process.

2. Three or more shellfish samples, (12 or more shellfish per sample) randomly selected from three or more locations in each tank, shall be collected for bacterial examination after 24 hours of depuration.

3. Three or more shellfish samples, (12 or more shellfish per sample) randomly selected from three or more locations in each tank, shall be collected for bacterial examination after the shellfish have completed the treatment process.

B. The above schedule shall be followed until such time as the Department of Health and Hospitals, after review of the results, determines that the shellfish from such areas are responding properly to the treatment process, and that the process is successfully reducing bacterial levels. After such a determination, a routine sampling procedure shall be followed that conforms with the requirements of the latest edition of the National Shellfish Sanitation Program Manual of Operations, Part II. Written permission from the Department of Health and Hospitals must be obtained prior to the initiation of routine monitoring procedures. A

bacteriological sampling program shall not be required for shellfish undergoing wet storage

C. In the event of the installation of a new laboratory, new laboratory equipment, employment of new laboratory personnel, initiation of new laboratory procedures, or the alteration of treatment or procedures, the Department of Health and Hospitals may require reinitiation of "start-up phase" procedures until such time as the department, after review of the results, determines that the laboratory and/or treatment procedures are providing valid results. Written permission from the department shall be obtained before routine monitoring procedures are again followed.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1229. Depuration and/or Wet Storage Process Water Control—Sampling [Formerly 49:6.1150]

A. All controlled processes require quality assurance testing to determine if standards are being met and if controls are effective. The treatment or wet storage of shellfish is a controlled process designed to reduce and/or maintain bacterial contamination to an acceptable level. To insure the continuing effectiveness of the shellfish treatment process, the minimum sampling procedure as described below, shall be followed:

B. Incoming Sea Water

1. Type of Test: temperature, turbidity, salinity, dissolved oxygen, bacteriological.

2. Frequency: prior to initiation of 48-hour treatment or wet storage process.

C. Effluent from Ultraviolet Light Treatment Unit

1. Type of Test: bacteriological

2. Frequency: once per day per unit.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1231. Depuration and/or Wet Storage Treatment Process Water Standards [Formerly 49:6.1160]

A. Bacteriological. All water to be used in shellfish treatment tanks shall be subjected to ultraviolet light treatment, or any other equally effective method of treatment approved by the Department of Health and Hospitals, National Shellfish Sanitation program manual of Operations, Part II, and the U.S. Food and Drug Administration. The treated water shall have bacterial quality equal to or better than the quality of water required in the U.S. Public Health Service Drinking Water Standards, as stated in Public Law 93-523 (Safe Drinking Water Act). The process water shall be treated daily. However, water from approved growing areas may be used in wet storage tanks without disinfection if the system used has a continuous flow-through design and provided that the near shore used for supplying the system meets the National Shellfish Sanitation Program approved area bacteriological criteria at all times that shellfish are being held for direct marketing.

B. Dissolved Oxygen. The amount of dissolved oxygen in the water in the treatment tanks shall be no less than 50 percent of saturation.

C. Temperature. Treatment tank water temperatures shall be measured daily during the treatment or wet storage process at the discharge end of the tanks. The temperatures of sea water shall be maintained between 10˚C and 35˚C.

D. Turbidity. Turbidity in the treatment process water shall not exceed a value capable of inhibiting the normal physiological activity of shellfish and/or would interfere with process water disinfection.

E. Salinity. Salinity of the process water shall not vary more than ± 20 percent of median salinity regimes of the harvest area.

F. Metallic Ions and Compounds. Levels of metallic ions and compounds shall not exceed levels found in approved shellfish harvesting areas and shall be measured if required by the Department of Health and Hospitals.

G. Pesticides, Detergents, and Radionuclides. Levels of pesticides, detergents, and/or radionuclides shall not exceed levels found in approved shellfish harvesting waters and shall be measured if required by the Department of Health and Hospitals

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1233. Table 1 [Formerly 49:6.1170]

Table 1. Depuration Treatment Process Water Standards

Parameter	Minimum	Maximum
Bacteriological (total coliform/100ml)	0	Less than 1
Dissolved Oxygen (percent saturation)	50%	100%
Temperature	10˚C	25°C
Turbity	0	*
Salinity	**	**
pH	7.0	8.4
Metallic Ions and Compounds		Not exceeding levels found in approved shellfish harvesting areas.
Pesticides, Detergents and Radionuclides		Not exceeding levels found in approved shellfish harvesting areas.

* to be established at each plant during process verification studies.
**Shall not vary more than ±20 percent of median salinity regimes of harvest area.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1235. Depuration—Shellfish Meat Standards [Formerly 49:6.1180]

A. Shellfish meats shall not be released for sale that do not meet the bacteriological standard for depurated shellfish set forth in the latest edition of the National Shellfish Sanitation Program Manual of Operations, Part II.

B. The use of the elevated temperature coliform plate count is authorized for the bacteriological evaluation of hard clams, *Mercenaria spp*., only.

C. Should the Department of Health and Hospitals suspect contamination of shellfish by metallic ions and compounds, pesticides, detergents, radionuclides, marine toxins, and/or any toxic substance or adulterate, the department may require that shellfish meats be analyzed for such contaminants before suspect shellfish are released for sale.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1237. Depuration and/or Wet Storage Treatment Unit [Formerly 49:6.1190]

A. Any water purification unit meeting the approval of the Department of Health Hospitals, the National Shellfish Sanitation Program, and the U.S. Food and Drug Administration may be used for the purification of process water. The unit shall be designed to deliver at peak load, at least one gallon per minute of treated water per bushel of shellfish.

B. Cautions and Maintenance

1. UV tubes shall be checked for intensity (commercial meters are available) on a monthly basis and shall be replaced when they reach a point of 60 percent efficiency. A log of intensity shall be kept and an orderly numbering procedure for units and bulbs established.

2. UV tubes and reflectors shall be cleaned daily. Cleaning may be done with a damp cloth and sponge.

3. Signs stating "Ultraviolet Light Danger to Eyes—Do not look at Bulbs Without Eye Protection" shall be displayed in full view of personnel and authorized visitors. Skin protection, especially for the face and hands, shall be provided for personnel monitoring the bulbs. Eye protection may be accomplished by use of ordinary glasses with solid side pieces or special goggles made for this purpose. Protection for the head may be afforded by a hat and hand protection may be accomplished by the use of gloves. Face protection may be afforded by the use of certain clear plastics.

4. An automatic shutoff switch shall be provided to break the electric circuit, thus shutting off the current to the UV bulb when the lid of the UV is raised.

5. A device of some kind, i.e., clock, off-on current recorder, etc., shall be installed in line with all UV units to measure continuity of operation as well as to measure bulb life.

6. The complete treatment system which includes all equipment surfaces that come into direct contact with treatment water and/or shellfish shall be cleaned and sanitized in conformance with approved procedures outlined in Chapter IX, Section 9:032 of the State Sanitary Code.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1239. Depuration—Shellstock Storage [Formerly 49:6.1210]

A. Refrigeration of Shellshock. Treated shellfish shall be placed under refrigeration immediately, and shall be stored at a temperature not to exceed 10°C. Refrigerated storage compartments shall be provided for treated shellfish, and all such shellfish shall be kept wholly separate from untreated shellfish. Said compartments shall be under supervision of the plant supervisor or assistant plant supervisor, and adequate measures shall be taken to prevent the unauthorized removal of any shellfish. All shellfish shall be handled and stored under such sanitary conditions as will protect the quality of the product.

B. Controlled Storage. Shellfish which are received at the treatment plant which cannot be processed immediately shall be placed in controlled storage. The temperature at which shellfish are held shall not vary more than plus or minus 6˚C from the temperature of the process water. (To avoid bacterial multiplication or spoilage of the shellfish, the maximum storage temperature shall be 21˚C.)

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985).

§1241. Depuration—Tagging and Release of Shellfish [Formerly 49:6.1210]

A. No shellfish shall be removed from the treatment plant until approved for release by the plant supervisor or assistant plant supervisor as provided in these rules and regulations. All containers of treated shellfish, before being

released from the depuration plant, shall be tagged in conformance with Chapter IX, Section 9:050, Louisiana State Sanitary Code as revised March 20, 1984. The tag shall also include the permit number given the treatment plant by the Department of Health and Human Resources and the date the shellfish were released from the treatment plant.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985).

§1243. Depuration and/or Wet Storage Records [Formerly 49:6.122]

A. Records containing the following information shall be available at the plant at all times for shellfish presently undergoing the treatment process:

1. parish(es) from which shellfish were harvested;

2. name, location and/or lease number(s) of harvesting area(s);

3. copy of relaying permit(s) (not applicable for wet storage);

4. date received;

5. quantity of shellfish in tank(s);

6. date and time of initiation of treatment or wet storage.

B. Records containing the following information shall be available at the depuration and/or wet storage plant at all times for each lot of shellfish which have completed the treatment process:

1. parish(es) from which shellfish were harvested;

2. name, location and/or lease number(s) of harvesting area(s);

3. copy of relaying permit(s) (not applicable for wet storage);

4. date received in plant;

5. date released from plant;

6. date and time of initiation of treatment or wet storage;

7. date and time of termination of treatment or wet storage;

8. number of hours treated;

9. all laboratory results as specified.

C. The plant supervisor or assistant plant supervisor shall send to the Department of Health and Hospitals, Office of Preventive and Public Health Services, Seafood Sanitation Unit P.O. Box 60630, New Orleans, LA 70160 on a weekly basis, a copy of the daily records required under this regulation and the results of all shellfish and water samples analyzed during that weekly period.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1245. Depuration and/or Wet Storage—Written Operating Procedures [Formerly 49:6.123]

A. Written detailed operating procedures for each depuration and/or wet storage plant shall be submitted by management to the Department of Health and Hospitals for approval prior to certification. The operating procedures shall comply fully with this regulation as well as all applicable sections of the latest edition of the National Shellfish Sanitation Program Manual of Operations, Part II.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990).

§1246. Depuration—Harvesting Permit [Formerly 49:6.140]

A. Any person, firm or corporation engaging in the business of harvesting shellfish for depuration purposes from areas not approved by the state health officer for direct market harvesting shall be required to have an unsuspended or unrevoked harvesting-for-depuration permit issued by the Department of Health and Hospitals. Growing waters to be utilized for harvesting purposes must meet or exceed the Department of Health and Hospitals' criteria for restricted area classification. A fee of $50 shall be charged for each 30-day permit.

B. Harvesting-for-depuration permits shall be granted only to responsible individuals with no recent history of illegal harvesting violations under the following conditions.

1. No permittee, vessel captain or crew member may serve on any vessel subject to this permit who has been cited or found guilty of violations relative to the harvesting of shellfish within three years of the application date; provided, however that said permittee, crew member or vessel captain may receive a waiver of this condition with regard to those citations which did not result in a conviction upon the appropriate showing being made to the Department of Wildlife and Fisheries.

2. A $5,000 cash performance bond consisting of a bank cashier's check or money order made payable to the Department of Health and Hospitals shall be posted by each permittee.

3. Harvesting and transporting of shellfish to depuration plants shall be permitted only during daylight hours with all activities completed no later than 30 minutes after official sunset each day.

4. The permittee shall be responsible for notifying the Department of Wildlife and Fisheries prior to leaving port to

fish under permitted conditions and immediately upon returning from permitted trip each day. The Department of Wildlife and Fisheries shall be notified by calling 1-800-442-2511.

5. All leases utilized for harvesting-for-depuration purposes shall be "red flagged" so that they may be easily spotted by both aircraft and boat. "Red flagged", as used in this paragraph, means that the four outside corners of a lease must be marked with poles with red flags attached.

6. The sacking of shellfish and the storage of empty shellfish sacks aboard permitted vessels is prohibited.

7. All harvesting and transporting of shellfish for delivery to a depuration plant shall be done in the direct line of sight of a commissioned municipal, parish, or state police officer, or bonded security guard from a state licensed agency. The payment of the surveillance officers salary and expenses shall be the responsibility of the permittee.

8. A maximum of five harvest boats may be included on one permit under the following conditions:

a. The permittee, vessel captain and crew members shall all be held liable for rule violations.

b. All vessels must be in direct line of sight of state approved surveillance officer during harvesting and transporting of shellfish to depuration plant.

c. Each permitted vessel shall have the permit number in at least 6-inch high letters on a contrasting background so as to be visible from low flying aircraft or from any other enforcement vessel in the immediate area.

9. Failure to comply with any of the permitting requirements specified in this Section shall result in the following administrative actions:

a. The harvesting-for-depuration permit and all permitting privileges shall be immediately suspended by the Department of Wildlife and Fisheries or the Department of Health and Hospitals.

b. All shellfish harvested-for-depuration purposes shall be returned to the original growing waters at permittee's expense.

c. If said charges are upheld in an administrative hearing, the following additional penalties shall be imposed:

i. harvesting-for-depuration and transplant permitting privileges shall be denied for a period of three years;

ii. the $5,000 cash bond posted by the permittee shall be forfeited and retained by the state.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:550 (May 1985), amended by the Department of Health and Hospitals, Office of Public Health LR16:414 (May 1990), amended LR 20:547 (May 1994), repromulgated LR 20:885 (August 1994).

Subchapter B. Certification Requirements for Shellfish Shippers

§1251. Definitions [Formerly 49:6.2010]

Certified Shellfish Shipper—any resident shucker-packer, repacker, reshipper, shellstock shipper, depuration processor, or wet storage processor who is certified by the Office of Public Health for inclusion on the U. S. Food and Drug Administration/Public Health Service's Interstate Shellfish Shippers List.

Critical Deficiency—a condition or practices which: a) results in the production of a product which is unwholesome; or b) presents a threat to the health or safety of consumers.

Depuration Processor (DP)—a person who receives shellstock from a conditionally restricted or restricted growing area and submits such shellstock to a state-approved depuration process.

Key Deficiency—a condition or practice which may result in an adulterated, decomposed, misbranded or unwholesome product.

Other Deficiency—a condition or practice that is not in accordance with NSSP Manual requirements but is not key or critical.

Repacker (RP)—a person other than the original certified shucker-packer who repacks shucked shellfish into other containers. A repacker may also repack and ship shellstock. A repacker shall not shuck shellfish.

Reshipper (RS)—a person who purchases shucked shellfish or shellstock from other certified shippers and sells the product without repacking or relabeling to other certified shippers, wholesalers, or retailers.

Shellfish—all edible species of oysters, clams, mussels, and scallops; either shucked or in the shell, fresh or frozen, whole or in part.

Shellstock Shipper (SS)—a person who grows, harvests, buys, or repacks and sells shellstock. They are not authorized to shuck shellfish nor to repack shucked shellfish. A shellstock shipper may also ship shucked shellfish originating from a certified shucker packer and packed in their original container.

Shucker-Packer (SP)—a person who shucks and packs shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

Wet Storage Processor (WS)—a person who receives shellstock from an approved or conditionally approved growing area and submits such shellstock to a state-approved wet storage process.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public

Health Services, LR 11:775 (August 1985), amended LR 20:548 (May 1994).

§1253. Certification Requirements for Resident Shellfish Shippers [Formerly 49:6.2020]

A. Resident shellfish shippers shall be certified annually and shall file an application for recertification each year with the Office of Public Health. An application for certification shall not be accepted from any individual or corporation previously found guilty within the past five years in a civil or criminal proceeding of knowingly selling shellfish that were harvested from waters not approved for shellfish harvesting by the state health officer. The Office of Public Health shall certify dealers for interstate shipment in accordance with the sanitation and administrative criteria contained in the 1994 edition of the National Shellfish Sanitation Program Manual of Operations, Parts I and II.

B. All applicants for certification or certification renewal shall undergo a comprehensive on-site inspection prior to being certified. The certification period shall not exceed 12 months. This comprehensive on-site inspection shall be conducted by an Office of Public Health standardized inspector within 30 days of the application for certification or renewal of certification, show the date of the on-site inspection, the inspector's full name and date of expiration of the inspector's standardization.

C. Only one certification number shall be issued to a dealer per location.

D.1 Certification shall be granted only to resident shippers who meet the following inspection requirements:

a. No critical deficiencies;

b. not more than two key item deficiencies; and

c. not more than three OTHER item deficiencies.

2. After a dealer is certified, unannounced inspections using an NSSP approved Office of Public Health inspection form shall be conducted during periods of operation and at such frequency as necessary to assure that adequate operational and sanitary conditions are maintained. A copy of the completed inspection form and a list of observations for items of noncompliance shall be provided to the most responsible individual at the firm.

E. The minimum frequency of inspection shall be:

1. within 30 days of beginning operation for any dealer certified on the basis of a preoperational inspection;

2. at least monthly for a depuration plant;

3. at least quarterly for shucker-packer and repacker;

4. at least semi-annually for other certified dealers.

F. Enforcement actions shall be taken as follows.

1. When a routine inspection detects a critical deficiency, the deficiency shall be corrected during the inspection or the plant must cease production affected by the deficiency. If the item is not corrected within the specified time, the Office of Public Health shall immediately begin actions to withdraw dealer certification. Further, product affected by the critical deficiency shall be controlled to prevent contaminated or adulterated product from reaching consumers.

2. When a routine inspection detects four or more key item deficiencies, a follow-up inspection shall be conducted as soon as possible but within 30 days. The follow-up inspection shall determine if the deficiencies have been corrected or are being corrected per the scheduled correction dates noted on the previous inspection report.

3. When the follow-up inspection of the key item deficiencies indicate a failure to comply with the correction schedule, the Office of Public Health shall immediately bring actions to suspend operations and withdraw dealer certification.

4. When a routine inspection detects other item deficiencies or three or less key item deficiencies, the deficiencies shall be corrected prior to the next routine inspection.

5. All specific deficiencies, as noted in the narrative section of the inspection report, which are repeated consecutively and are not corrected as scheduled shall be corrected prior to the annual certification. Dealers which fail to correct such deficiencies shall not be certified.

6. When inspections are made of certified shellfish shippers where the Office of Public Health finds nonconformities that present an imminent threat to public health, actions shall be initiated immediately by the Office of Public Health to suspend operations and withdraw certification until a reinspection confirms that appropriate corrections have been made. The Office of Public Health shall also seize any undistributed lots of shellfish that may have been adulterated, initiate a recall of shellfish distributed intrastate, and notify FDA and receiving state enforcement agencies of interstate product distributions.

7. When inspections are made of certified shellfish shippers where the Office of Public Health finds major public health deficiencies, action shall be initiated by the Office of Public Health to suspend or withdraw certification until a reinspection confirms that appropriate corrections have been made.

8. When a certificate is removed for cause, the Office of Public Health shall immediately notify FDA and shellfish control personnel in known receiving states.

G. A certified shellfish dealer whose certificate has been removed for cause may not ship shellfish in intrastate or interstate commerce until the Office of Public Health is satisfied that corrections have been made. A recertification shall not be issued until an inspection by the officer of public health establishes that the firm is in substantial compliance with all applicable criteria of the latest edition of the National Shellfish Sanitation Program Manual of Operations, Parts I and II. Upon recertification, the Office of Public Health shall notify FDA and known receiving

states immediately. These changes shall become effective April 20, 1994.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:775 (August 1985), amended by the Department of Health and Hospitals, Office of Public Health, LR 20:548 (May 1994).

§1255. Decertification or Denial of Certification of Shellfish Shippers [Formerly 49:6.2030]

A. The certification of shellfish shippers handling or making shipments of shell stock may be suspended revoked for failing to comply with any one of the four basic requirements or maintaining certification previously listed.

B. An application for certification shall not be accepted from any individual or corporation previously found guilty in a civil or criminal proceeding of knowingly selling shellfish that were harvested from waters not approved for shellfish harvesting by the State Health Officer.

C. Any individual or corporation currently charged by any State or Federal regulatory agency with harvesting or knowingly selling shellfish from waters not approved by the State Health Officer shall be ineligible for certification until all charges have been dismissed, or until found innocent of said charges.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 11:775 (August 1985).

Subchapter C. Shrimp for Freezing Regulations

§1261. Permit Requirement [Formerly 49:6.3010]

A. The following regulations shall apply to all Sea Food Dealers who deal in shrimp for freezing.

1. The peeling or packing of shrimp is prohibited, unless the operator of the establishment has an unsuspended or unrevoked permit to operate issued by the State Board of Health. Upon receipt of an application for permit to operate, an inspection will be made by a representative of the State Board of Health, and if the establishment is found properly equipped, in accordance with regulations, a permit will be issued authorizing the owner or operator of said establishment to engage in the business of peeling or otherwise preparing for packing fresh shrimp for freezing.

2. Such a permit may be suspended or revoked at any time for violation of these regulations. A suspended or revoked permit may be reinstated or re—issued when the proper improvements have been made.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: State of Louisiana Food, Drug and Cosmetics Laws and Regulations were filed with the Office of the State Register, by the Department of Health and Human Resources, Office of Preventive and Public Health Services, January 1, 1975.

§1263. General Operating Requirements [Formerly 49:6.3020]

A. The shrimp shall be emptied into a metal washing compartment and shall be carried from there by an inspection belt of sufficient length to allow adequate inspection for the removal of all shrimp which are in an unsatisfactory condition.

B. On leaving the inspection belt, shrimp shall be caught in metal baskets or containers for delivery to the tables where the heads or hulls are to be removed.

C. All edible portions left after the hulls or heads have been removed shall be promptly flumed to a metal skimmer for further inspection.

D. On leaving the skimmer, shrimp shall be placed in a metal tank containing ice water and crushed ice in sufficient quantity to maintain the temperature of the water at a temperature not to exceed 40°F.

E. Shrimp, with the heads removed that are to be transported to some other location for packing into unit containers for freezing shall, after thorough chilling in the crushed ice and water solution, be packed with a sufficient amount of ice to maintain the headless shrimp at or below a temperature of 40°F. until they are received at the packing plant.

F. When headless shrimp are packed in unit containers for freezing, either in the plant where the heads are removed or in the repacking plant, the packing shall be done as promptly as possible on metal tables.

G. When headless shrimp are packed in unit containers in the establishment where the heads are removed and are transported from there to a freezing plant, the unit packages shall be packed promptly in crushed ice so that there is no delay in the cooling of the shrimp after being packed.

H. All containers in which headless or peeled shrimp are to be packed for freezing shall be dipped in a chlorine solution of not less than 50 p.p.m. immediately before being filled with shrimp.

I. All utensils used in the handling of headless or peeled shrimp, and all tables, skimmers, conveyers and other equipment, shall be treated each day by washing or rinsing in a chlorine solution of not less than 200 p.p.m. before the plant starts operation.

J. The ice water solution used for cooling the headless or peeled shrimp shall be drained off after each two hours' use, or less if used for less than that length of time; and the tank shall be washed and treated with a chlorine solution of not less than 200 p.p.m. after which the tank shall be rinsed out with potable water.

K. All peeled shrimp for freezing shall be packed, in the containers in which they will be frozen, in the plant where the peeling operations are carried on.

L. The packing of headless or peeled shrimp in containers other than those bearing the permit number of the plant in which the shrimp are packed is prohibited.

M. All containers intended for use for packing shrimp for freezing shall be subject to seizure unless properly numbered with the permit number issued by the Department of Health and Human Resources.

N. The peeling of shrimp, and packing in bulk containers for transportation to some other establishment for packing into unit containers in which the shrimp will be frozen, is prohibited. The packing of shrimp which have been peeled at some other establishment is also prohibited.

O. All cartons or containers in which headless or peeled shrimp are packed for freezing must be printed, stamped, embossed, or otherwise labeled with the number of the permit from the Department of Health and Human Resources authorizing the packer to operate. This permit number must appear in addition to any other labeling which might be on the carton or other container.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: State of Louisiana Food, Drug and Cosmetics Laws and Regulations were filed with the Office of the State Register, by the Department of Health and Human Resources, Office of Preventive and Public Health Services, January 1, 1975.

§1265. Physical Requirements [Formerly 49:6.3030]

A. All exterior openings of the establishment shall be adequately screened, and roofs and exterior walls shall be tight. When necessary, fly traps or other approved insect—control devices shall be installed.

B. Except for raw headless shrimp, which may or may not be deveined, picking and packing rooms shall be separate, provided that this requirement may be waived where separation of picking and packing rooms is not necessary for adequate sanitation. Fixtures and equipment of picking and packing rooms shall be so constructed and arranged as to permit thorough cleaning. Such rooms shall be adequately lighted and ventilated, and the floors thereof shall be tight and arranged for thorough cleaning and proper drainage. Open drains from picking rooms shall not enter packing room. If picking and packing rooms are in separate buildings, such buildings shall not be more than 100 yards apart unless adequate provisions are made to enable efficient inspection.

C. All surfaces of tanks, belts, tables, flumes, utensils, and other equipment with which either picked or unpicked shrimp come in contact after delivery to the establishment shall be of metal other than lead, or of other nonporous and easily cleanable materials. Metal seams shall be smoothly soldered or smoothly welded.

D. Adequate supplies of nontoxic detergents, sanitizing agents, potable running water and, if necessary, of steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

E. Adequate toilet facilities of sanitary type shall be provided. Full compliance must be met with the requirements of State laws, City ordinances, or both.

F. An adequate number of sanitary wash basins, with liquid or powdered soap, shall be provided in both the picking and packing rooms, paper towels shall be provided in the packing room.

G. Signs requiring employees handling shrimp to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the picking and packing rooms and elsewhere about the establishment as conditions require.

H. One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the shrimp before processing.

I. Suitable containers, flumes, chutes, or conveyors shall be provided for removal of offal from picking room.

J. Picking or heading tables shall be equipped with flumes supplied with potable water or with mechanical conveyors for removing the picked or headed shrimp.

K. Each freezing and cold—storage compartment shall be fitted with at least the following equipment:

1. an automatic control for regulating temperatures;

2. an indicating thermometer so installed as to indicate accurately the temperature within the freezing or storage compartment.

L. Provisions shall be made for water—glazing where such glazing is necessary to maintain the quality of the frozen shrimp. Glazing shall be done with potable water.

M. Provisions shall be made for the immediate icing or cold storage of all packaged shrimp which is destined for sale or unfrozen shrimp.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: State of Louisiana Food, Drug and Cosmetics Laws and Regulations were filed with the Office of the State Register, by the Department of Health and Human Resources, Office of Preventive and Public Health Services, January 1, 1975.

§1267. Miscellaneous Requirements [Formerly 49:6.3040]

A. The decks and holds of boats catching shrimp for, or transporting shrimp to, an inspected establishment, and the bodies of other conveyances so transporting shrimp shall be kept in a sanitary condition. The shrimp shall be iced or refrigerated immediately after they are caught, and shall be kept adequately iced or refrigerated until delivery to the establishment. Heading of shrimp on boats catching them will be permitted if the shrimp are headed immediately after

catching, washed before and after heading and then immediately iced or refrigerated.

B. Inspected establishments, freight boats, and other conveyances serving such establishments shall accept only fresh, clean, sound shrimp.

C. After delivery of each load of shrimp to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with potable water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

D. Before picking, heading, or deveining, the shrimp shall be adequately washed with potable water and then passed over the inspection belt and culled to remove all shrimp that are filthy, decomposed, putrid, or otherwise unfit for food, and all extraneous material.

E. Offal from picking tables shall not be piled on the floor, but shall be placed in suitable containers for frequent removal of shall be removed by flumes, conveyors, or chutes.

AUTHORITY NOTE: Promulgated in accordance with Louisiana Revised Statutes of 1950, Title 40, as amended.

HISTORICAL NOTE: State of Louisiana Food, Drug and Cosmetics Laws and Regulations were filed with the Office of the State Register, by the Department of Health and Human Resources, Office of Preventive and Public Health Services, January 1, 1975.

Chapter 13. Regulation of Tanning Facilities and Equipment:

§1301. Purpose and Scope [Formerly 49:8.0000]

A. These regulations provide for the registration, certification and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the living human body through the application of ultraviolet radiation.

B. The current statutory provisions in R.S. 40:2701 through 2719, as enacted by Act No. 587 of 1990, indicates that the owner or proprietor of each tanning parlor facility must apply for a certificate of registration as well as a separate permit from the Department of Health and Hospitals. In order to implement Act No. 587 of 1990 efficiently, and to accomplish the desired regulatory results in the best interest of the public health, the department will require a single application to register and obtain a permit for each tanning parlor facility in the state. Upon completion of processing, which includes inspection of each such facility by a department employee, only a single certificate of registration and permit will be issued. The combined instrument will expire at midnight on the date specified on the face of the document, and it must be renewed annually, as further specified in these regulations.

C. Nothing in these regulations shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or therapy other than skin tanning, provided such treatment or therapy is supervised by a licensed practitioner of the healing arts in the lawful practice of their profession, in accordance with the requirements of their professional licensing board to prescribe and supervise such treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2657 (December 2015).

§1303. Authority [Formerly 49:8.0010]

A. These regulations are promulgated under authority of the Tanning Facility Regulation Act comprising R.S. 40:2701 through 2719 (Act No. 587 of 1990), as amended by Act No. 193 of 2014.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2658 (December 2015).

§1305. Definitions [Formerly 49:8.0020]

Act—Tanning Facility Regulation Act, unless the text clearly indicates a different meaning. All definitions and interpretations of terms given in the Act shall be applicable also to such terms when used in these regulations.

Authorized Agent—an employee of the department designated by the state health officer to enforce the provisions of the Act. The responsibility for implementing the provisions of the Act has been assigned to the Food and Drug Unit of the Office of Public Health of the Department of Health and Hospitals.

Consumer—any individual who is provided access to a tanning facility which is required to be registered pursuant to provisions of these regulations.

Department—the Department of Health and Hospitals.

Formal Training—a course of instruction approved by the department and presented under formal classroom conditions by a qualified expert possessing adequate knowledge and experience to offer a curriculum, associated training, and certification testing pertaining to and associated with the correct use of tanning equipment.

Individual—any human being.

Operator—any individual designated by the registrant to operate or to assist and instruct the consumer in the operation and use of the tanning facility or tanning equipment.

Persons—any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision or agency thereof, and any

legal successor, representative, agent, or agency of these entities.

Phototherapy Device—a piece of equipment that emits ultraviolet radiation and is used by a licensed health care professional in the treatment of disease.

Registrant—any person who has filed for and received a certificate of registration-permit issued by the department as required by provisions of these regulations.

Secretary—the secretary of the Department of Health and Hospitals.

State Health Officer—the employee of the department who is the chief health care official of the state as provided for in R.S. 40:2.

Tanning Equipment—ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body with ultraviolet radiation.

Tanning Facility—any location, place, area, structure, or business which provides consumers access to tanning equipment. For the purpose of this definition, tanning equipment. For the purpose of this definition, tanning equipment registered to different persons at the same location and tanning equipment registered to the same persons, but at separate locations, shall constitute separate tanning facilities.

Ultraviolet Radiation—electromagnetic radiation with wavelengths in air between 200 nanometers and 400 nanometers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:209 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2658 (December 2015).

§1307. Exemptions [Formerly 49:8.0030

A. As provided in R.S. 40:2704, any person is exempt from the provisions of these regulations to the extent that such person:

1. uses equipment which emits ultraviolet radiation incidental to its normal operation;

2. does not use the equipment described in Paragraph 1 of this Subsection to deliberately expose parts of the living human body to ultraviolet radiation for the purpose of tanning or other treatment.

B. Any physician licensed by the Louisiana State Board of Medical Examiners is exempt from the provisions of these regulations and is authorized to use a phototherapy device or other medical diagnostic and the therapeutic equipment which emits ultraviolet radiation.

C. Any individual is exempt from the provisions of these regulations to the extent that such individual owns tanning equipment exclusively for non-commercial use.

D. Tanning equipment while in transit or storage incidental thereto is exempt from the provisions of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:209 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2658 (December 2015).

§1309. Certificate of Registration—Permit [Formerly 49:8.0040]

A. Each person owning or operating a tanning facility or facilities within the state of Louisiana shall apply for a certificate of registration-permit for each such facility or facilities no later than April 1, 1992.

B. The application for a certificate of registration-permit required above shall be made on forms provided by the department and shall contain all the information required by such forms and any accompanying instructions.

C. The application for certificate of registration-permit shall include the information required in R.S. 40:2705(D).

D. A fee of $150 shall accompany each initial application for a certificate of registration-permit

E. Each tanning facility operating within the state for which an application for registration-permit and fee has been received by the department shall be issued a temporary registration- permit until such time that an inspection of the tanning facility and equipment can be made and it is determined that a permanent registration- permit to operate can be issued.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:209 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1311. Issuance of Certificate of Registration—Permit [Formerly 49:8.0050]

A. A certificate of registration-permit shall be issued upon receipt of an application provided that no certificate of registration-permit be issued until inspection has been made of the tanning facility and it has been found to be operating in compliance with the provisions of the Act and these regulations.

B. The certificate of registration-permit shall be displayed in an open public area of the tanning facility.

C. An annual certificate of registration-permit shall be issued upon receipt of an application of forms provided by the department for this purpose and required renewal fees.

D. A certificate of registration-permit shall be issued only to the person or persons responsible for the operations of the tanning facility and shall not be transferable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1313. Renewal of Registration—Permit [Formerly 49:8.0060]

A. The registrant shall file applications for renewal of certificate of registration-permit on forms provided by the department. The application shall be sent to the mailing address of the principal registrant listed on the last application for registration-permit submitted.

B. An annual renewal fee of $110 shall accompany each annual renewal. Make check or money order payable to the Food and Drug Unit/Department of Health and Hospitals.

C. Provided that a registrant files an application with the department in proper form not less than thirty days prior to the expiration date stated on the certificate of registration-permit, the certificate shall not expire pending final action on the application by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:209 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1315. Report of Changes [Formerly 49:8.0070]

A. The registrant shall notify the department in writing before making any change which would render the information contained in the application for certificate of registration-permit inaccurate. Notification of changes shall include information required by R.S. 40:2705(D)1, 2, 3, 4, 6.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1317. Transfer of Certificate of Registration—Permit [Formerly 49:8.0080]

A. No certificate of registration-permit may be transferred from one person to another or from one tanning facility to another tanning facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1319. Prohibited Acts; Advertisement [Formerly 49:8.0090]

A. A tanning facility may not claim or distribute promotional materials that claim use of a tanning device is safe or free from risk.

B. No person shall state or imply that any activity under such certificate of registration-permit has been approved by the department.

C. No person or tanning facility may claim health benefits from the use of a tanning device unless such claims have been approved in advance by the state health officer.

D. No tanning facility may allow any person under eighteen years of age to use any tanning equipment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:210 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1321. Denial, Suspension, or Revocation of a Certificate of Registration—Permit [Formerly 49:8.0100]

A. The department may deny, suspend, or revoke a certificate of registration-permit applied for or issued pursuant to these regulations:

1. for any material false statement in the application for certificate of registration-permit or in any statement of fact required by provisions of this Chapter;

2. because of conditions revealed by the application or any report, record, inspection or other means which would warrant the department to refuse to grant a certificate of registration-permit on an original application;

3. for operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety;

4. for failure to allow authorized representatives of the department to enter the tanning facility during normal business hours for the purpose of determining compliance with the provisions of these regulations, the Tanning Facility Regulation Act, conditions of the certificate of registration-permit, or an order of the department;

5. for violation of or failure to observe any of the terms and conditions of the certificate of registration, the provisions of this Chapter, or an order of the department;

6. failure to pay a certificate of registration-permit fee or annual renewal fee;

7. the registrant obtained or attempted to obtain a certificate of registration-permit by fraud or deception;

8. the operation of a tanning facility without a valid certificate of registration-permit or the continued operation

after a certificate has been revoked or suspended, shall constitute a violation of these regulations. Each day of noncompliance shall constitute a separate violation.

B. Except in cases of willful disregard for the public health and safety, prior to the institution of proceedings for suspension or revocation of a certificate of registrant-permit, the agency shall:

1. call to the attention of the registrant in writing, the facts or conduct which may warrant such actions;

2. provide reasonable and sufficient opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

C. The department may deny a certificate of registration-permit or suspend or revoke a certificate of registration-permit after issuance only in accordance with the Administrative Procedure Act.

D. The department may terminate a certificate of registration-permit upon receipt of a written request for termination from the registrant.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:210 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2659 (December 2015).

§1323. Compliance with Federal and State Law [Formerly 49:8.0110]

A. Tanning devices used by a tanning facility shall comply with 21 *Code of Federal Regulations* (CFR) part 1040.20, sunlamp products and ultraviolet lamps intended for use in sunlamp products.

B. Except as otherwise ordered or approved by the department, each tanning facility shall be constructed, operated, and maintained in accordance with the requirements of R.S. 40:2710 through 40:2714.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2660 (December 2015).

§1325. Warning Signs Required [Formerly 49:8.0120]

A. The registrant shall conspicuously post the warning sign described in Subsection B of this Section within three feet of each tanning station and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the consumer before energizing the tanning equipment.

B. The sign required by this Section shall be printed in upper and lower case letters which are at least one-half inch and one-quarter inch in height, respectively, and shall contain the following warnings:

Danger—Ultraviolet Radiation

- Follow instructions.
- Avoid overexposure. As with natural sunlight, repeated exposure to ultraviolet radiation can cause chronic sun damage characterized by premature aging of the skin, wrinkling, dryness, fragility and bruising of the skin, and skin cancer.
- Wear protective eyewear.

Failure to Use Protective Eyewear May Result in Severe Burns or Permanent Injury to the Eyes.

- Medications or cosmetics may increase your sensitivity to the ultraviolet radiation.
- Consult a physician before using sunlamp or tanning equipment if you are using medications or have a history of skin problems or believe that you are especially sensitive to sunlight. Pregnant women or women taking oral contraceptives who use this product may develop discolored skin.

If You Do Not Tan in the Sun, You are Unlikely to Tan from the Use of Ultraviolet Radiation of Tanning Equipment.

C. Each registrant shall place, at the entrance of the tanning facility, signage that states the following: "LOUISIANA LAW PROHIBITS PERSONS UNDER 18 YEARS OF AGE FROM USING ANY TANNING FACILITY EQUIPMENT THAT EMITS ULTRAVIOLET LIGHT FOR THE PURPOSE OF SKIN TANNING"; this sign shall be of dimensions of at least eight inches by ten inches.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:210 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2660 (December 2015).

§1327. Tanning Equipment Standards [Formerly 49:8.0130]

A. Equipment used in tanning facilities shall conform to the standards set forth in R.S. 40:2711(A) through (D) as well as the following.

1. Tanning equipment booths or rooms shall be of rigid construction.

2. Wall surfaces within booths or rooms shall be easily cleanable and shall be kept clean at all times.

3. Ceilings, where provided, shall be easily cleanable and shall be kept clean.

4. Floors within tanning equipment booths or rooms shall be constructed of readily cleanable materials including, but not limited to, vinyl tile, sheet vinyl, quarry tile, glazed brick, short pile carpet or rugs, or other suitable material.

5. Floors shall be kept clean and in good repair at all times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit,

LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2660 (December 2015).

§1329. Requirements for Stand-Up Booths [Formerly 49:8.0140]

A. Tanning booths designed for stand-up use shall also comply with the requirements of R.S. 40:2712.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2661 (December 2015).

§1331. Potable Water Supply; Sanitary Facilities; Sewage and Waste Disposal [Formerly 49:8.0150]

A. Each tanning facility shall provide an ample supply of potable hot and cold water, under pressure for drinking, cleansing, washing or other purposes. Such water supply shall not be cross connected to any other supply.

B. Each tanning facility shall provide toilet and hand washing facilities according to requirements of Part XIV, Table 411 of the state *Sanitary Code* and each toilet shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing. Toilet rooms shall be well lighted and ventilated.

C. Sewage disposal shall be made in a sewage system or by other means approved by the State Health Officer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2661 (December 2015).

§1333. Rubbish and Trash Disposal [Formerly 49:8.0160]

A. Rubbish, trash, and other debris including used or burned out tanning lamps shall be so conveyed, stored and disposed of as to minimize the development of odor and to prevent harborage of vermin.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2661 (December 2015).

§1335. Operational Requirements [Formerly 49:8.0170]

A. Each tanning facility must be operated under the requirements set forth by R.S. 40:2713.

B. Each tanning facility shall establish and adhere to effective procedures for cleaning and sanitizing each tanning bed or booth as well as protective eyewear before and after use of such equipment by each consumer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:210 (February 1993), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2661 (December 2015).

§1337. Information Provided to Consumers, Warnings [Formerly 49:8.0180]

A. Each tanning facility operator shall provide each consumer, prior to initial exposure, a written warning statement as required by R.S. 40:2714(A). Such warning statements shall be signed by each consumer and maintained permanently on file at the tanning facility. A copy of the signed warning statement shall be given to each consumer. Copies of such warning statement shall be available for review during inspections by duly authorized agents of the state health officer. The written warning statement shall warn that:

1. failure to use eye protection provided to the customer by the tanning facility may result in damage to the eyes;

2. overexposure to ultraviolet light causes burns;

3. repeated exposure may result in premature aging of the skin and skin cancer;

4. abnormal skin sensitivity or burning may be caused by reactions of ultraviolet light to certain:

a. foods;

b. cosmetic;

c. medications, including tranquilizers, diuretics, antibiotic, high blood pressure medicines, and oral contraceptives;

5. any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device;

6. a person should not sunbathe before or after exposure to ultraviolet radiation from sunlamps.

B. Consumer warning statements acknowledged by each consumer by signature prior to initial exposure shall be maintained on file within the tanning facility and shall be made readily available for review by authorized agents of the Department of Health and Hospitals, Office of Public Health.

C. The registrant shall maintain for six years a record of each consumer's total number of tanning visits, dates, and duration of tanning exposures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended LR 19:210 (February 1993),

amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2661 (December 2015).

§1339. Reports to the Department [formerly 49:8.0190]

A. The registrant shall submit to the department a written report of actual or alleged injury from the use of registered tanning equipment within five working days after occurrence or notice thereof as required by R.S. 40:2714(D). The report shall include:

1. the name of the affected individual;

2. the name, location, and number of the certificate of registration-permit for the tanning facility and identification of the specific tanning equipment involved, including the name, model number, date of manufacture and type of lamp(s);

3. the nature of the actual or alleged injury, as well as the complete name, address and telephone number of any doctor visited for medical attention;

5. any other information relevant to the actual or alleged injury, including the date and duration of exposure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 41:2662 (December 2015).

§1341. Replacement of Ultraviolet Lamps, Bulbs, Filters [Formerly 49:8.0210]

A. Defective and burned out lamps, bulbs, or filters shall be replaced in accordance with R.S. 40:2714(F) and (G).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2662 (December 2015).

§1343. Tanning Equipment Operator Training [Formerly 49:8.0220]

A. The registrant shall certify that all tanning equipment operators are adequately trained in at least the following:

1. the requirements of these regulations;

2. procedures for correct operation of the tanning facility and tanning equipment;

3. recognition of injury or overexposure to ultraviolet radiation;

4. the tanning equipment manufacturer's procedures for operation and maintenance of the tanning equipment;

5. the determination of skin type of consumers and appropriate determination of duration of exposure to registered tanning equipment;

6. emergency procedure to be followed in case of injury.

B. The registrant shall limit the operation of tanning equipment to persons who have successfully completed formal training courses which cover the provisions of Paragraph A.1 of this Subsection, and have been approved by the department.

C. The registrant shall maintain a record of operator training required in Paragraph A.2 of this Subsection for inspection by authorized representatives of the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2662 (December 2015).

§1345. Inspections by Department [Formerly 49:8.0230]

A. In order to effect the enforcement of these regulations, officers or employees duly authorized by the department or the state health officer, after making reasonable request, may enter any registered or unregistered tanning facility and inspect all tanning booths, rooms, tanning equipment, tanning devices, consumer records, and any other materials used in the tanning facility.

B. No tanning facility registrant, owner, or operator shall refuse this reasonable inspection request, without being subjected to provisions of §1321.A.4 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2662 (December 2015).

§1347. Penalties; Criminal Penalty; Injunction [Formerly 49:8.0240]

A. Criminal penalties or injunctions may be imposed upon a tanning facility operator as provided by 40:2716 and 40:2717 of the Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2701-2719.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Food and Drug Unit, LR 18: 274 (March 1992), amended by the Department of Health and Hospitals, Office of Public Health, LR 41:2662 (December 2015).