DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH
FOOD & DRUG UNIT

BASIC REQUIREMENTS FOR PROSPECTIVE DRUG MANUFACTURERS

(Revised 3/5/10)

A. PERMITS.

1. **Plans Review:** No person shall operate a facility engaged in the manufacturing, processing, packing or holding of drugs or cosmetics within Louisiana without a valid permit to operate issued by the State Health Officer through the Food & Drug Unit of the Office of Public Health. Permits to Operate expire annually on June 30. The permit fee for drug manufacturers, processors, packers, and re-packers will be calculated on a sliding scale based on the gross annual sales of the establishment. Forms for reporting the gross annual sales can be obtained from the program coordinator assigned to your region/district. Permit fees are assessed as follows:

Based on gross annual sales	
Less than $500,000	$175
$500,001 - $1,000,000	$475
$1,000,001 - $2,500,000	$775
$2,500,000 - $5,000,000	$1,075
Greater than $5,000,000	$1,375

In addition, the local Parish Health Unit should be contacted regarding the approval status of the source of potable water and the method of wastewater disposal. For new construction, if a sewer is not available, it may be required to apply for and install an onsite wastewater disposal system. A link to the locations of Parish Health Units may be found here: http://www.dhh.louisiana.gov/offices/?ID=223.

2. **Product Registration:** As required by the State Food, Drug and Cosmetic Law, each manufacturer, processor, packer or private-label distributor of drugs or cosmetics in package form must register each separate and distinct product annually. Firms shall submit to the Food & Drug Unit a completed Application for Registration Form [FD-9(N)] together with copies of labels for each item and applicable registration fees. The registration fee is currently $20.00 per separate and distinct product up to a maximum charge of $200.00 per year. **Please note that more than 10 separate package types may be**

registered by a given corporation—*and copies of all labels must be sent to OPH*—but only the first 10 types are charged a registration fee.

B. FDA FACILITY REGISTRATION.

Note that drug-manufacturing facilities have long been required to maintain registration information on sites and products with FDA. More information on registration for facilities manufacturing pharmaceuticals may be found here http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm) and information for manufacturers of biologics (blood products, other tissue products, and vaccines) may be found here (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm).

C. RELEVANT STATUTES/REGULATIONS.

Attached are the following rules and regulations pertaining to the manufacture of drugs in the state of Louisiana:

1. Louisiana State, Food, Drug, and Cosmetic Law (LSA R.S. 40: §601 *et seq*)
2. Louisiana State Food, Drug, and Cosmetic Regulations, Drug Regulations (49:4.0010-49:4.0570)
3. Part VI, Title 51 of the Louisiana Administrative Code, Chapter 15, Current Good Manufacturing Practices in the Manufacture of Drugs

LOUISIANA REVISED STATUTES TITLE 40

CHAPTER 4. FOOD AND DRUGS

PART I. ADULTERATION, SUBSTITUTION, MISBRANDING,

OR FALSE ADVERTISING

§601. Title

This Part may be cited as the "State Food, Drug, and Cosmetic Law."

§602. Definition of terms

As used in this Part, unless the context otherwise indicates, the following terms shall have the meaning ascribed to them in this Section:

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

(2) "Cosmetic" includes all substances and preparations intended for cleansing, 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.

(3) "Department" means the Department of Health and Hospitals and "secretary" means the secretary thereof.

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

(5) "Drug" includes all substances and preparations recognized in the official compendium, as herein defined. It includes all substances and preparations intended for use in the diagnosis, treatment, 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.

(6) "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.

(7) "Label" means the principal display or displays of written, printed, or graphic matter upon any food, drug, device, or cosmetic, or the immediate container thereof, or upon the outside container or wrapper, if any, of the retail package of any food, drug, device, or cosmetic.

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

(9) "Medical opinion" means 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.

(10) "Medical profession" means the legalized profession of the healing art.

(11) "Official compendium" means the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, National Formulary, or any supplement of any of them, official at the time any drug, to which the provisions thereof relate, is introduced into commerce.

(12) "Scientific opinion" means the opinion, within their respective fields, of competent pharmacologists, physiologists, or toxicologists.

Amended by Acts 1978, No. 786 §5, eff. July 17, 1978.

§603. Liability of persons

When construing and enforcing the provisions of this Part, unless otherwise provided, the act or omission of any officer, employee, or agent acting for or employed by any person, within the scope of employment or office, shall in every case be considered the act or omission of such person, as well as that of the officer, employee, or agent.

Whenever a corporation or association violates any of the provisions of this Part, unless otherwise provided, the violation shall also be considered a violation by the individual directors, officers or agents of the corporation or association who personally ordered or did any of the acts constituting the violation, in whole or in part.

§604. Regulations

The authority to promulgate regulations for the efficient enforcement of this Part is vested in the secretary of the Department of Health and Hospitals.

Amended by Acts 1978 No. 786, §5, eff. July 17, 1978.

§605. Examinations, investigations, and hearings conducted by board or agent

The department, or any designated officer or employee thereof, may conduct examinations and investigations for purposes of this Part.

Hearings authorized or required by this Part shall be conducted by the department or the officer or employee designated by it for the purpose.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§606. Court review of regulations and administrative actions; injunctions

On the petition of any interested person, the district courts may:

(1) Restrain by injunction, temporary or permanent, the enforcement by an officer, representative, or employee of the department of any regulation promulgated by it under the provisions of this Part if it is shown that the regulation is unreasonable, arbitrary, or capricious, or not in accordance with the facts or law, and that the petitioner may suffer substantial damage by reason of its enforcement; and

(2) Grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the department in the administration of this Part, if it has been shown that the act or omission is unreasonable, arbitrary or capricious, or not in accordance with the facts or law and that petitioner may suffer substantial damage thereby.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§607. Adulterated food

A. A food is considered adulterated if it has been found to be such by any department of the United States government, or:

(1) If it contains any poisonous or deleterious substances, added or otherwise, which may render it dangerous to health; or any added poisonous or deleterious substance which is prohibited by R.S. 40:611 or which is in excess of the limits of tolerance prescribed by regulations of the department.

(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

(3) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

(4) If it is the product of a diseased animal or of an animal which has died otherwise than by slaughter.

(5) If its container is composed of any poisonous or deleterious substance which may render the contents injurious to health.

(6) If any valuable constituent has been in whole or in part abstracted therefrom.

(7) If any substance has been substituted wholly or in part therefor.

(8) If damage or inferiority has been concealed in any manner.

(9) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, reduce its quality or strength, or create a deceptive appearance.

(10) If it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations of the department.

(11) If it is confectionery or ice cream and it contains any alcohol, resinous glaze, or nonnutritive substance, except harmless coloring, harmless resinous glaze, harmless flavoring, natural gum, and pectin; provided, that this Paragraph shall not apply to any confectionery by reason of its containing less than ten percent by volume of alcohol or to any chewing gum by reason of its containing harmless nonnutritive masticatory substance.

B. The department shall promulgate sanitary regulations for implementing the provisions in Paragraphs (2) and (3) of this Section.

C. For the first charge and finding thereunder the person shall be given a notice and hearing and a notice to correct the unsanitary conditions or the unsanitary food complained of. This notice and order does not prohibit the seizure of food dangerous to health as provided in this Part.

D. For purposes of this Section:

(1) Anyone who sells confectionery that contains more than one-half of one percent alcohol rendered unfit for beverage purposes to a person who is under the legal age for purchasing alcoholic beverages shall be fined not more than three hundred dollars or imprisoned for not more than six months, or both.

(2) Any confectionery manufactured in this state that contains more than one-half of one percent alcohol rendered unfit for beverage purposes shall bear a label containing the statement: "Sale of this product to persons under the legal age for purchasing alcoholic beverages is unlawful." A person who violates the provisions of this Paragraph shall be fined not more than three hundred dollars or imprisoned for not more than six months, or both.

(3) No confectionery containing more than one-half of one percent alcohol rendered unfit for beverage purposes shall be sold in this state unless the product bears a label that meets the requirements of Paragraph (2) of this Subsection or a sign containing the statement: "Sale of confectionery containing more than one-half of one percent alcohol to persons under the legal age for purchasing alcoholic beverages is unlawful" is displayed at the place where the product is sold or offered for sale. A person who violates the provisions of this Paragraph shall be fined not more than three hundred dollars or imprisoned for not more than six months, or both.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978; Acts 1988, No. 654, §1.

§608. Misbranded food

A food is considered to be misbranded if it has been found to be such by any department of the United States government, or:

(1) If its labeling is false or misleading in any particular.

(2) If it is offered for sale under the name of another food.

(3) If it is an imitation of another food and its label fails to bear, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(4) If its container is so made, formed, or filled as to mislead the purchaser.

(5) If it is in package form and does not bear a label containing (a) the name and place of business of the manufacturer, packer, distributor, or seller; and (b) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. For the purposes of Subparagraph (b) of this Paragraph, reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations of the department.

(6) If any word, statement, or other information required on the label under any provision of this Part is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily understood by purchasers and users of the articles under customary conditions of purchase and use. Due consideration shall be given to the size of the package.

(7) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations of the department and (a) it does not conform to the definition and standard, (b) its label does not bear the name of the food prescribed in the definition and standard, or (c) when the definition and standard permits optional ingredients other than spices, flavors, and coloring, its label does not bear the common names of the optional ingredients present in it, if those names are required by the regulations.

(8) If it purports to be or is represented as a food for which a standard of quality or fill of container has been prescribed by regulations of the department and its quality or fill falls below that standard and its label fails to bear a statement, in the manner specified in the regulations, showing that it falls below the standard.

(9) If it is not subject to the provisions of Paragraph (7) of this Section and its label fails to bear (a) the common or usual name of the food, if any, and, (b) in case it is fabricated from two or more ingredients, the common or usual name of each ingredient. Spices,

flavors, coloring, other than those sold as such, may be designated as spices, flavors, and colorings without naming each. To the extent that compliance with the requirements of Subparagraph (b) of this Paragraph is impracticable because of variations in ingredients usual to good manufacturing or packing practice or is impracticable for any other reason, exemptions shall be established by regulations promulgated by the department. Subparagraph (b) of this Paragraph does not apply to any proprietary food the ingredients of which have been fully and correctly disclosed to the department if compliance with the Subparagraph would give competitors information they could not otherwise obtain.

The department shall establish regulations for implementing the provisions of this Paragraph and publish from time to time the list of ingredients required herein to be declared on the label. However, these lists shall be within the class of ingredients required to be declared on the label under this Paragraph.

(10) If it purports to be or is represented as being for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value.

The department shall establish regulations for implementing the provisions of this Paragraph, including administrative regulations covering vitamin, mineral, and other dietary properties. These regulations shall be established in cooperation with the United States Public Health Service, with a view particularly to the work of that service connected with pellagra and other dietary diseases and the feeding of children, so that the inspection to determine correct labeling shall fully conform to the work of the public health service, as far as that work goes.

(11) If it bears or contains any artificial flavor, artificial color, or chemical preservative and it fails to bear a label stating that fact.

(12) If bottled water to be sold in the state for human consumption, is not labeled to indicate the source of the water, the methods used to treat the contents to reduce or eliminate impurities, and the chemical names and concentrations of any preservatives or additives.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978; Acts 1982, No. 608, §1.

§608.1. Mislabeling of honey

A. It is unlawful for any person to package any product and label the product as honey or to use the word honey in any prominent location on the label of such product or to sell or offer for sale any product which is labeled as honey or which contains a label with the word honey prominently displayed thereon, unless such product is pure honey manufactured by honeybees.

B. Any person violating the provisions of this section shall be guilty of a misdemeanor and upon conviction shall be fined not less than fifty dollars nor more than five hundred dollars and each such violation shall constitute a separate offense.

Added by Acts 1974, No. 143, §1.

§608.2. Unlawful practices in sale of kosher food; penalty

A. It shall be unlawful for any person to:

(1) Sell or expose for sale with intent to defraud in any place where food products are sold for consumption either on or off the premises, any article of food falsely represented as kosher, either by direct statements, orally or in writing, or by the display of the word kosher in English or Hebrew letters, or by the display of any sign or mark in simulation of such word, or by display of any insignia, six pointed star, or any mark which might reasonably be calculated to deceive or lead a reasonable person to believe that a representation is being made that the food exposed for sale is kosher, or prepared in accordance with orthodox Hebrew religious requirements; or

(2) Sell or expose for sale with intent to defraud any meat or meat preparations and falsely represent the same to be kosher, with intent to defraud, whether such meat or meat preparations be raw or prepared for human consumption, or as having been prepared under and a product or products sanctioned by the orthodox Hebrew religious requirements; or

(3) Falsely represent with intent to defraud any food product or the contents of any package or container to be so constituted and prepared, by having or permitting to be inscribed thereon the word kosher in any language.

B. The word kosher as used in Subsection A of this Section shall mean in conformity with orthodox Jewish religious requirements.

C. Any person violating the provisions of this Section shall be guilty of a misdemeanor and upon conviction shall be fined not more than five hundred dollars and each such violation shall constitute a separate offense.

Added by Acts 1977, No. 722, §1.

§608.3. Labeling of organic food

A. No person shall use the term "organic food" or any derivative of the term "organic" in the labeling or advertising of a food, unless the growth and composition of such food product meets the following requirements:

(1) The organic food is grown, raised, or composed of ingredients that were grown or raised without the use of synthetic fertilizers, pesticides, hormones, antibiotics, growth

stimulants, and arsenicals. Other natural substances, such as diatomaceous earth, soaps, elemental sulfur, lime sulfur, and basic copper sulfate, may be used in the growing of organic food.

(2) Soil on which organic food is grown or raised shall be free of synthetic fertilizers, pesticides, hormones, antibiotics, growth stimulants, and arsenicals for at least one year prior to planting.

B. Under the provisions of this Section, "organic food" means any food product, including meat, dairy products, and beverages, that is marketed using the term "organic" or any derivative of the term "organic" in its labeling or advertising.

C. Every grower and manufacturer of any product identified as organic shall provide the Department of Agriculture and Forestry, upon demand, with relevant information which is required pursuant to the provisions of this Section.

D. The Department of Agriculture and Forestry may withhold from sale or trade any product sold, labeled, or advertised in violation of this Section.

E. The Department of Agriculture and Forestry may adopt rules and regulations, including emergency rules, necessary to clarify organic food standards and marketing practices under the provisions of this Section.

F. The provisions of this Section shall be implemented only when funds are appropriated for that purpose.

G. Any person violating the provisions of this Section shall be subject to a civil fine of not more than five hundred dollars, and each such violation shall constitute a separate offense.

Added by Acts 1989, No. 825, §1.

§609. Exemption from labeling requirements

The department may promulgate regulations exempting from any labeling requirement of this Part small open containers of fresh fruits and fresh vegetables and also food which is, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that the food is in conformity with the provisions of this Part upon removal from the processing, labeling, or repacking establishment.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§610. Definitions and standards for food

The department may promulgate regulations fixing and establishing for any food a definition and standard of identity and a reasonable standard of quality or fill of container. However, no standard of quality shall be established for fresh fruit and fresh vegetables and no standard of identity for fresh apples and fresh pears. In any regulation pertaining to fill of container the department shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to the need for the necessary packing and protective material.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§611. Tolerance for poisonous ingredients in food and certification of coal-tar colors for food

A. No poisonous or deleterious substance shall be added to any food unless it is required in the production of the food or cannot be avoided by good manufacturing practice. When such a substance is required or cannot be avoided, the department may, for the protection of public health, promulgate regulations limiting the quantity therein or thereon.

In determining the quantity of added substance to be tolerated in or on different articles of food, the department shall take into account the extent to which the use of this substance is required or cannot be avoided in the production of each such article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

B. The department may promulgate regulations for the certification of coal-tar colors which are harmless and suitable for use in food.

This certificate shall contain the physiological factors tested and give notice that only those factors have been tested.

No person shall use this certificate in the label or advertising of any food.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§612. Contaminated food; permit control

Whenever the department finds, after investigation, that the distribution of any class of food may, by reason of contamination with microorganism during the manufacture, processing, or packing thereof, is injurious to health, and such injurious nature cannot be adequately determined after the articles have entered state commerce, it may then, and in that case only, promulgate regulations, governing the conditions of manufacture, processing, or packing for such temporary periods of time as may be necessary to protect the public health. Thereafter, no manufacturer, processor, or packer of that class of articles shall introduce into state commerce any such food unless he holds an unsuspended, valid permit issued by the department as provided by the regulations.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§613. Regulations governing issuance and renewal of permit

The department shall make regulations prescribing the time for which the permits are issued and governing the issuance and renewal thereof.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§614. Suspension of permit; reinstatement

Upon notice to the permittee, the secretary of the department may suspend immediately any permit issued under authority of R.S. 40:612 if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended may apply at any time for its reinstatement. After a prompt hearing and an inspection of the establishment, the department shall immediately reinstate the permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§615. Inspection of permittee's establishment; denial of access

Any officer or employee duly designated by the department has access to any factory or establishment, the operator of which holds a permit from the department, for the purpose of ascertaining whether or not the conditions of the permit are being complied with. Denial of access for this inspection is grounds for suspension of the permit until the access is freely given by the operator.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§616. Adulterated drugs

A drug is considered adulterated if it has been found to be such by any department of the United States government, or:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(2) If it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health.

(3) If its container is composed of any poisonous or deleterious substance which may render it injurious to health.

(4) If it contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with department regulations.

(5) If its name is recognized in the official compendium, or if it purports to be a drug the name of which is so recognized, and it differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth in the official compendium or in the regulations of the department, unless its standard of strength, quality, or purity is plainly stated on its label.

However, no such department regulation shall be adopted unless tests or methods of assay have not been prescribed in the official compendium or the tests or methods of assay prescribed therein are insufficient and, after due notice by the department of that fact, the official body in charge of the revision of the compendium has not corrected the deficiency.

(6) If it is not subject to the provisions of paragraph (5) of this Section and its identity or strength differs from or its purity or quality falls below that which it purports or is represented to possess.

(7) If any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefor.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§617. Misbranded drugs and devices

A. A drug or device is considered misbranded if it has been found to be such by any department of the United States government, or:

(1) If its labeling is false or misleading in any particular. Any representation concerning any effect of a drug or device is considered false for purposes of this Paragraph if the representation is not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion.

(2) If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof.

(3) If it is in package form and it does not bear a label containing: (a) the name and place of business of the manufacturer, packer, seller, or distributor; and (b) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Under Subparagraph (b) of this Paragraph reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the department where compliance with the provisions would be impracticable.

(3.1) If it is a prescription drug bearing the following words "Caution: Federal law prohibits dispensing without a prescription", and (a) the manufacturer, packager, seller, or

distributor of any prescription drug sold, delivered, or offered for sale in the state of Louisiana after January 1, 1976, does not have printed on the label on the immediate container of the drug the name and place of business of the manufacturer and, if different, the name and place of business of the packer or distributor of the final dosage form of the drug; and (b) the manufacturer, packager, seller, or distributor does not have printed on the label on the final dosage form an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Under Subparagraph (b) of this Paragraph reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the department where compliance with the provisions would be impracticable. Wholesalers or jobbers who sell prescription drugs only to retailers or institutions shall be exempt from the provisions of this Paragraph. However, nothing contained in the provisions of this Paragraph shall affect the labeling requirements of a prescription label placed on a container by a pharmacist in the process of dispensing a prescription drug.

(3.2) If it contains any quantity of amyl nitrite, isopentyl nitrite or any of their isomers, or butyl nitrite, n-butyl nitrite, isobutyl nitrite or any of their isomers, and is not labeled "Caution: Louisiana Law prohibits dispensing without a prescription" and its sale is not restricted to the prescription of a physician, except that amyl nitrite may be labeled in accordance with labeling requirements of the Federal Food, Drug and Cosmetic Law.

(4) If any information required on the label under any provision of this Part is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily understood by purchasers and users of the articles under customary conditions of purchase and use. Due consideration shall be given to the size of the package.

(5) If it is for use by man and contains any quantity of any of the following narcotic or hypnotic substances and, except when dispensed on the written order of a member of the medical profession, its label fails to bear the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement "Warning--May be Habit Forming": Alpha eucaine, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, sulphomethane, or any substance chemically derived therefrom, except derivatives of coca leaves which do not contain cocaine, ecgonine (or substances from which cocaine or ecgonine may be synthesized or made) or any other narcotic or hypnotic substance designated as habit forming by regulations of the department, unless the derivative is clearly not habit forming.

(6) If it is a drug and is not designated solely by a name recognized by an official compendium or if its label has been disapproved by the United States government or the department.

(7) If its name is recognized in an official compendium, or if it purports to be a drug the name of which is so recognized, and it is not packaged and labeled as prescribed therein.

(8) If it is a drug liable to deterioration and is not packaged in the form or manner required by department regulations for the protection of public health or its label does not bear a statement of those precautions.

No such regulation shall be established for any drug recognized in the official compendium until the department shall have informed the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and that body shall have failed within a reasonable time to prescribe those requirements.

(9) If it is a drug and its container is so made, formed, or filled as to mislead the purchaser.

(10) If it is a drug and it is an imitation of another drug.

(11) If it is a drug and it is offered for sale under the name of another drug.

B. When construing and enforcing the provisions of this Part with respect to labeling and advertisements, the term "antiseptic" has the same meaning as the word "germicide", except, however, in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or for such other use as involves prolonged contact with the body.

Amended by Acts 1975, No. 524, §1; Acts 1978, No. 140, §1; Acts 1978, No. 786, §5, eff. July 17, 1978.

§617.1. Distribution of imitation controlled dangerous substances to a person under eighteen

A. A person eighteen years of age or over shall not knowingly or intentionally distribute or possess with intent to distribute an imitation controlled dangerous substance representing it to be a controlled dangerous substance to a person under eighteen years of age.

B. A person eighteen years of age or over shall not knowingly or intentionally distribute or possess with intent to distribute an imitation controlled dangerous substance intending it to be used or distributed as a controlled dangerous substance or under circumstances in which the person has reasonable cause to believe that the imitation controlled dangerous substance will be used or distributed for use as a controlled dangerous substance.

C. "Imitation controlled dangerous substance" means a substance that is a noncontrolled substance, but which by appearance or operation, including color, shape, size, markings, or packaging, or by representations made, or by its pharmacological effect, would lead a reasonable person to believe that the substance is a controlled dangerous substance.

D. It is not a defense that the accused believed the imitation controlled dangerous substance to be a controlled dangerous substance.

E. Whoever commits the crime of distribution of an imitation controlled dangerous substance to a person under eighteen shall be imprisoned with or without hard labor for not more than five years and may be fined not more than five thousand dollars.

Acts 1992, No. 1059, §1; Acts 1993, No. 154, §1.

§618. Drugs recognized in compendiums

Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia for purposes of this Part unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

§619. Certain drugs and devices excepted from labeling and packaging provisions

The department shall promulgate regulations exempting from any labeling or packaging requirement of this Part drugs and devices which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that these drugs and devices are in conformity with the provisions of this Part upon removal from the processing, labeling, or repacking establishment.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§620. Certification of coal-tar colors for drugs

The department may promulgate regulations for the certification of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§621. Adulterated cosmetics

A cosmetic is considered adulterated if it has been found to be such by any department of the United States government, or:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health under such conditions of use as are customary or usual.

(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

(4) If its container is composed of any poisonous or deleterious substance which may render it injurious to health.

(5) If it contains a coal-tar color other than one from a batch that has been certified in accordance with regulations of the department.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§622. Misbranded cosmetics

A cosmetic is considered misbranded if it has been found to be such by any department of the United States government, or:

(1) If its labeling is false or misleading in any particular or if it is injurious to health under the conditions of use prescribed in the labeling or advertising thereof.

(2) If it is in package form and it does not bear a label containing: (a) the name and place of business of the manufacturer, packer, seller, or distributor; and (b) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, under Subparagraph (b) of this Paragraph reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the department where compliance with that provision would be impracticable.

(3) If any word, statement, or other information required on the label under any provision of this Part is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily understood by the purchasers and users of the articles under customary conditions of purchase and use. Due consideration shall be given to the size of the package.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§623. Certain cosmetics excepted from labeling requirements

The department may promulgate regulations excepting from any labeling requirements of this Part cosmetics which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that these cosmetics are in conformity with the provisions of this Part upon removal from the processing, labeling, or repacking establishment.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§624. Certification of coal-tar colors for cosmetics

The department may promulgate regulations for the certification of coal-tar colors which are harmless and suitable for use in cosmetics.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§625. False advertisement

A. An advertisement of a food, drug, device, or cosmetic is false if it is false or misleading in any particular regarding the food, drug, device, or cosmetic. Any representation concerning any effect of a drug or device is false under this Sub-section if it is not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion.

B. Except as provided below, the advertisement of a drug or device representing it to have any therapeutic effect in the treatment of Bright's disease, cancer, tuberculosis, poliomyelitis, venereal disease, heart and vascular diseases, or any other diseases for which no known therapeutic effect has been fully established is false. No advertisement not in violation of Sub-section A of this Section shall be considered false under this Sub-section, if it is disseminated only to members of the medical and pharmaceutical professions or appears only in the scientific periodicals of these professions, or if it is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of the drugs or devices.

C. Except as provided in R.S. 40:626, it is unlawful for any person to disseminate false advertisement by any means for the purposes of inducing, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

§626. Exceptions as to false advertising by agencies

Publishers, radio broadcast licensees, television broadcast licensees, advertising agencies, and other agencies or mediums for dissemination of advertising do not violate the provisions of R.S. 40:625(C) by the dissemination of any false advertisement when the dissemination is caused by the manufacturer, packer, distributor, or seller who resides in Louisiana. However, the manufacturer, packer, distributor, or seller is amenable to the prosecution and penalties provided for the violations of that Subsection. No publisher, radio broadcast licensee, television broadcast licensee, advertising agency, or other agency or medium for the dissemination of advertising shall willfully refuse, on reasonable request of an officer or employee duly designated by the department, to furnish to the officer or employee the name and post office address of the manufacturer, packer, distributor, or seller, residing in Louisiana, who caused him to disseminate any such advertisement.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§627. Registration of certain products

A. The department may require all manufacturers, packers, or proprietors of processed foods, proprietary or patent medicines, prophylactic devices, and cosmetics, in package form, to register each separate and distinct product annually with the department and to supply it with a sample of each such product upon request.

B. The submission of a catalog and specimens of labels shall be required at the time of application for registration of products produced, packaged, and prepared in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, which will constitute satisfactory compliance for registration of the products. With respect to all other products, submission of a catalog and specimens of labels shall be required at the time of application for registration, but registration will not become effective until examination and approval of the label or product by the department. This approval shall be by written notification to the manufacturer, packer, or processor.

C. No manufacturer, packer, or proprietor shall sell any product which he has failed to register in conformity with this Section. Such failure also subjects the product to seizure and condemnation as provided by R.S. 40:632 through R.S. 40:634.

D. The department shall assess each manufacturer, packer, or proprietor a penalty of ten dollars for failure to register each separate and distinct product annually as provided in this Section. The penalty assessed shall be in addition to the examination and investigation charge assessed as provided in R.S. 40:628(B). Each failure to register a separate and distinct product shall constitute a separate violation. However, no manufacturer, packer, or proprietor shall be assessed more than one hundred dollars in any calendar year. The department shall promulgate rules and regulations to provide for assessment and collection of the penalty provided in this Subsection.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978; Acts 1983, 1st Ex. Sess., No. 10, §1, eff. Jan. 19, 1983; Acts 1985, No. 344, §1, eff. Feb. 1, 1986.

§628. Examination and investigation fee; food and drug control fees

A. All inspection, investigation, and examination fees collected by the department under the provisions of this Part shall be devoted to the expenses of inspections, examinations, and investigations conducted under the authority of this Part and for the maintenance and enforcement of the provisions of this Part.

B. The department shall charge and collect from the manufacturers, packers, or proprietors of the products referred to in R.S. 40:627 an annual examination and investigation charge of not more than twenty-seven dollars for any one separate and distinct product registered, up to a maximum of two hundred seventy dollars annually from each manufacturer, packer, or proprietor. Manufacturers, packers, or proprietors of soft drinks and nonalcoholic beverages, except nonalcoholic fruit juices, and manufacturers, packers, or proprietors of products offered for sale or sold at retail only in their own establishments are exempt from the payment of examination and investigation charges here authorized.

C. The department shall charge and collect an annual food and drug control permit fee from manufacturers, packers, and processors of foods, drugs, and cosmetics. The fee shall not apply to any plant required to have a commercial seafood permit pursuant to R.S. 40:31.35. This Section shall not apply to meat packers, meat processors, and meat warehouses, or agricultural commodities or any combination thereof, regulated by the state Department of Agriculture and Forestry. The fee shall be for each separate establishment for which a permit is required based on the annual sales of such establishment according to the following schedule:

Annual sales

Annual fee

Under $500,000

$ 175.00

$500,001 - $1,000,000

475.00

$1,000,001 - $2,500,000

775.00

$2,500,001 - $5,000,000

1,075.00

over $5,000,000

1,375.00

D. The department shall charge and collect an annual food and drug control fee of three hundred dollars from warehouses and distributors of foods, drugs, and cosmetics. The fee shall be for each separate establishment for which a permit is required.

Amended by Acts 1954, No. 472, §1; Acts 1978, No. 786, §5, eff. July 17, 1978; Acts 1985, No. 344, §1, eff. Feb. 1, 1986; Acts 2000, 1st Ex. Sess., No. 125, §1, eff. July 1, 2000.

§629. Records of interstate shipment

A. For the purpose of enforcing the provisions of this Part, carriers engaged in interstate commerce and persons receiving food, drugs, devices, or cosmetics in interstate commerce shall, upon the request in the manner set out below of an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.

B. The request provided for in this Section shall be accompanied by a definite statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which it relates.

C. Evidence obtained under this Section shall not be used in criminal prosecution of the person from whom obtained.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§630. Carriers in interstate commerce; excepted from Part

Carriers engaged in interstate commerce are not subject to the provisions of this Part, other than R.S. 40:629, by reason of their receipt, carriage, or delivery of food, drugs, devices, cosmetics, or advertising matter in the usual course of business as carriers.

§631. Factory inspections

A. In order to prevent commerce in adulterated or misbranded food, drugs, devices, or cosmetics and to safeguard the public health and prevent deceit upon the purchasing public, officers or employees duly designated by the department, after making reasonable request, may enter any factory, warehouse, or other establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held for storage or shipment in commerce or are held after such shipment, or any vehicle being used to transport food, drugs, devices, or cosmetics in commerce and inspect the factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

B. No owner, operator, or custodian of such a place shall refuse this reasonable request, under pain of the penalties provided in this Part.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§632. Causes for seizure and condemnation of food, drugs, devices, or cosmetics

Any article of food and any drug, device, or cosmetic that is adulterated, misbranded, or unregistered or which has been manufactured, processed, or packed in a factory or establishment, the operator of which did not, at the time of manufacture, processing, or

packing, hold an unsuspended valid permit, if so required under R.S. 40:612, is subject to seizure and condemnation by the department or by any officer or employee it designates for that purpose.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§633. Seizure; procedure; prohibition on sale or disposal of article

A. Whenever a duly authorized officer or employee of the department finds or has probable cause to believe that cause for the seizure of any food, drug, device, or cosmetic, as set out in R.S. 40:632 exists, he shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being subject to seizure under the provisions of R.S. 40:632 and that it has been detained and seized by the department. He shall also warn all persons not to remove or dispose of the article by sale or otherwise, until permission of the department or of the court of the jurisdiction in which the article is detained or seized is given.

B. It is unlawful for any person to remove or dispose of the detained or seized article by sale or otherwise without permission of the department or of the court in such cases.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§634. Condemnation and sale, or release

When any article detained or seized under R.S. 40:633 has been found by the department to be subject to seizure and condemnation under R.S. 40:632, the department shall petition a court for an order of condemnation or sale, as the court may direct. The proceeds of the sale minus the legal costs and charges shall be paid into the state treasury to the credit of the general fund.

Upon the payment of the costs of the condemnation proceeding and upon the execution and delivery of a surety bond to the effect that the goods shall not be sold or otherwise disposed of contrary to the provisions of this Part, the department or court may order that the goods be delivered to the owner thereof instead of being condemned or sold.

If the department finds that any article seized under the provisions of R.S. 40:633 was not subject to seizure under that Section, the department or the designated officer or employee shall remove the tag or marking.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§635. Condemnation or destruction of perishables in certain cases

Whenever the department or its duly authorized officer or employee finds in any factory, establishment, structure, or vehicle of transportation any meat, seafood, poultry, vegetables, fruit, or other perishable articles which are unsound or contain any filthy,

decomposed, or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe for human consumption, the officer or employee of the department designated by it shall immediately condemn or destroy it or in any other manner render it unconsumable as human food.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§636. Other prohibited acts

The following acts and the causing thereof are prohibited:

(1) The introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(2) The adulteration, or misbranding, of any food, drug, device, or cosmetic in commerce.

(3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.

(4) The forging, counterfeiting, simulating, or falsely representing or, without proper authority, using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this Part.

(5) The possession in any place where sales or service is made to the public of any food, drug, device or cosmetic that is adulterated or misbranded.

(6) The using by any person to his own advantage, or the revealing, other than to the department, its officers or employees, or to the courts when relevant in the trial of any case under this Part, any information acquired under authority of R.S. 40:612 through R.S. 40:615 or R.S. 40:631 concerning any method or process which, as a trade secret, is entitled to protection.

Amended by Acts 1952, No. 482, §1; Acts 1978, No. 786, §5, eff. July 17, 1978.

§637. Procedure for reporting violations of Part

A. Before reporting any violation of this Part to any district attorney for institution of criminal proceedings thereunder, the department may, in accordance with regulations prescribed by it, afford appropriate notice and opportunity for hearing to interested persons upon the question of such violations. The report to the district attorney when such hearings are held shall be accompanied by findings of the appropriate officers and employees.

B. The department need not report for prosecution minor violations of this Part when the purposes of the Part can best be accomplished by a suitable written notice or warning.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978; Acts 1985, No. 346, §1, eff. July 9, 1985.

§638. Duties of district attorney

Each district attorney to whom the department reports any violation for institution of criminal or injunction proceedings under this Part, or to whom any health, food, or drug officer of the state or political subdivision thereof, presents evidence satisfactory to the district attorney, of any such violation, shall institute appropriate proceedings in the proper court without delay.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

§639. Penalties

Whoever violates any provision of this Part shall be fined, for the first offense, not more than one thousand dollars or imprisoned for not more than one year, or both. For the second or subsequent offense, he shall be fined not more than three thousand dollars or imprisoned for not more than two years, or both. But any person who violates the provisions of Sub-section C of R.S. 40:625 shall only be fined not more than one thousand dollars for each violation if the violation does not involve gross deception or imminent danger to health, and is established by opinion evidence only.

§640. Dealers excepted from penalty in certain cases

No dealer is subject to the penalties of R.S. 40:639:

(1) For having received any article of food, drug, device, or cosmetic and in good faith sold it as received unless he refuses to furnish on request of an officer or employee duly designated by the department the name and address of the person from whom he purchased or received the article and all documents pertaining to the delivery of the article to him, or

(2) If he established a guaranty or undertaking signed by the person residing in Louisiana from whom he received in good faith the article of food, drug, device, or cosmetic, or advertising copy thereof to the effect that the designated article is not adulterated or misbranded within the meaning of this Part and that the copy is not false. To afford protection, this guaranty or undertaking shall contain the name and address of the person furnishing it. This person shall be amenable to the prosecution and penalties which would attach in due course to the dealer under the provisions of this Part.

Amended by Acts 1950, No. 316, §11. Acts 1978, No. 786, §5, eff. July 17, 1978.

§641. Injunction proceedings

In order to avoid multiplicity of criminal prosecutions, the district courts may, for cause, restrain any person by temporary or permanent injunction from the repetitious introduction or causing to be introduced into commerce of any adulterated, misbranded, or unregistered food, drug, device, or cosmetic; or from the dissemination or causing to be disseminated of a false advertisement by any means for the purpose of inducing, directly or indirectly, the purchase of food, drugs, devices, or cosmetics in commerce.

In these injunction proceedings it is not necessary to show an intent on the part of the person enjoined to continue the offense.

Violation of any injunction issued pursuant to this Section shall be summarily tried and punished by the court as a contempt. The contempt proceedings may be instituted by order of the court or by the filing of an information by the district attorney and process of the court for the arrest of the violator may be served at any place in the state.

No person violates any injunction issued pursuant to this Section by reason of the dissemination, subsequent to the injunction, of the false advertisement which was the basis of the injunction, if the dissemination was beyond the control of the person.

§642. Reports by department

A. The department shall, from time to time, have reports published summarizing all judgments, decrees, and court orders which have been rendered under this Part, including the nature of the charge and the disposition thereof.

B. The department may also disseminate information regarding food, drugs, devices, or cosmetics in cases involving imminent danger to health or gross deception of the consumer.

C. Nothing in this Section prohibits the department from collecting, reporting, and illustrating the results of its investigations.

Amended by Acts 1978, No. 786, §5, eff. July 17, 1978.

LOUISIANA STATE FOOD, DRUG, AND COSMETIC REGULATIONS
Chapter 4, Part I

DRUG REGULATIONS

49:4.0010 Drug name

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.

49:4.0020 Drug name, differs from official compendium

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.

49:4.0030 Misbranding, false or misleading representation

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.

49:4.0040 Misbranding, name suggest only one ingredient

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 suggest the name of one or more but not of all the ingredients stated elsewhere in the labeling.

49:4.0050 Misbranding, firm name and address on label

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.

49:4.0060 Misbranding, name of the place of business

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.

49:4.0070 Misbranding prohibited

The label shall contain the name and place of business of the manufacturer, packer or distributor and such aspect of the label shall not be misleading in any way.

49:4.0080 Quantity of contents

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.

49:4.0090 Quantity of contents, expression of

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 a tablet, capsule, ampule 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, ampule 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.

49:4.0100 Quantity of contents, devices

The statement of the quantity of a device shall be expressed in terms of a numerical count.

49:4.0110 Quantity of contents, terms used

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, and shall express the volume at 68°F (20°C).

49:4.0120 Quantity of contents, use of fractions

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.

49:4.0130 Quantity of contents, use of largest units

Except as provided for in paragraph 4.0140, a statement of the quantity of a drug in the terms of weight or measure applicable to such drug under the provisions of .4.0090 shall express the number of the largest unit specified in 4.0110 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 4.0110. For example, "1 ¼ pounds" may be expressed as "1 pound 4 ounces." The stated number of any units smaller than the largest unit (as specified in 4.0110) 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 ½ quarts or 1 quart 1 pint."

49:4.0140 Quantity of contents, customary usage

In the case of 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 customers.

49:4.0150 Quantity of contents, minimum quantity

The statement of the quantity of 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 ampules. When in ampules, the statement of the quantity of the contents of a drug shall be considered to express the minimum quantity.

49:4.0160 Quantity of contents, variation from minimum quantity

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 ampules, the variation

above the stated measure shall comply with the excess volume prescribed by any official compendium for the filling of ampules.

49:4.0170 Quantity of contents, where minimum quantity not expressed

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.

49:4.0180 Quantity of contents, variations

The extent of variations from the stated quantity of the contents permissible under paragraphs 4.0160 and 4.0170 shall be determined by the facts in the case of each shipment or other delivery.

49:4.0190 Quantity of contents statements, exemptions

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 4.0080, 4.0090, 4.0100, 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 wit the requirements of R.S. 40: 617-A(3) and regulations promulgated thereunder; or

(2) The quantity of contents of the package, as expressed in terms of numerical count in compliance with paragraph 4.0090 or 4.0100 is less than six units, and the units can be easily counted without opening the package.

49:4.0200 Misbranding, prominence and conspicuousness of words

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 9(d) 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 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 therefore, 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 a word; 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.

49:4.0210 Labeling exemptions prohibited

No exemption depending on insufficiency of label space, as prescribed in relation to 4.0190 and 4.0440 promulgated under R.S. 40: 617-A(3), (6), and (7) shall apply if 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 Section 9(c) of the Act; or
(3) the use of label space for any representation in a foreign language

49:4.0220 English language required

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.

49:4.0230 Foreign language labeling

If 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.

49:4.0240 Official names required

The name of a substance or derivative required to be borne on the label of a drug by regulation 4.0310 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 complies with the provisions of R.S. 40: 617-A(4).

49:4.0250 Names of narcotic and hypnotic substances

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.

49:4.0260 Habit-forming drugs

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	Name of chemical derivative	Chemical formula of derivative
Barbituric acid	Alurate	5-allyl-5-isopropyl-barbituric acid
	Amytal	5-ethyl-5-isoamyl-barbituric acid
	Barbital	5,5-diethyl barbituric acid
	Butisol	5-ethyl 5-*sec*-butyl-barbituric acid
	Cyclopal, cyclopen	5-allyl-5-cyclopanteyl-barbituric acid
	Delvinal	5-ethyl-5-(1-methyl-1-butenyl)-barbituric acid
	Dial	5,5-diallyl-barbituric acid
	Eldoral	5-ethyl-5-(1-piperidyl)-barbituric acid
	Eunacron	5-(2-bromoallyl)-5-isopropyl-1-methyl-barbituric acid
	Evipal	1,5-dimethyl-5-(1-cyclohexenyl)-barbituric acid
	Ipral	5-ethyl-5-isopropyl-barbituric acid
	Mebaral	5-ethyl-5-phenyl-1-methyl-barbituric acid
	Nacronumal	5-allyl-5-isopropyl-1-methyl-barbituric acid
	Neonal	5-ethyl-5-butyl-barbituric acid
	Nostal	5-isopropyl-5-(2-bromoallyl)-barbituric acid
	Ortal	5-ethyl-5-hexyl-barbituric acid

Barbituric acid	Pentenal	5-ethyl-5-cyclopentenyl-barbituric acid
	Pentobarbital	5-ethyl-5-(1-methyl-butyl)-barbituric acid
	Pentothal	5-ethyl-5-(1-methyl-butyl)-2-thio-barbituric acid
	Pernoston	5-*sec*-butyl-5-(2-bromoallyl)-barbituric acid
	Phanodorn	5-ethyl-5-(1-cyclohexenyl)-barbituric acid
	Phenobarbital	5-ethyl-5-phenyl-barbituric acid
	Proponal	5,5-dipropyl-barbituric acid
	Rutonal	5-methyl-5-phenyl-barbituric acid
	Sandoptal	5-allyl-5-isobutyl-barbituric acid
	Sigmodal, Rectidon	5-(2-bromoallyl)-5-(1-methylbutyl)-barbituric acid
	All lithium, sodium, potassium, magnesium, calcium, strontium, and ammonium salts of the above derivatives of barbituric acid	
	Seconal	Sodium-5-allyl-5-(1-methylbutyl)-barbituric acid
	All salts of seconal formed by replacing the sodium with lithium, potassium, magnesium, calcium, strontium, or ammonium	
Bromal	Bromal hydrate	Tribromoacetaldehyde hydrate
	Brometone	2-(tribromomethyl)-2-propanol
	Bromoform	Tribromomethane
Cannabis	Extract of cannabis, fluid extract of cannabis, tincture of cannabis	
Carbromal	Acetylcarbromal	A-bromo-α-ethyl-butrylacetyl-urea
	Bromural	A-bromoisovaleryl-urea
	Neuronal	A-bromo-α,α-diethyl-acetamide
Chloral	Sedormid	A-allylisovaleryl-urea
	A-chloralose	A-(β-trichloro-α-hydroxy-ethyl)-δ-glucoside
	Chloralformamide	N-(β-trichloro-α-hydroxy-ethyl)-formamide
	Chloral hydrate	Trichloroacetaldehyde hydrate
	Chloralimide	Trichloroethyl-ideneimime
	Chlorobutanol	2-(tricholoromethyl)-2-propanol
Cocaine	All salts of cocaine obtained by combining cocaine with any acid	
Codeine	Dicodid	Dihydrocodeinone
	Eucodal	Dihdroxycodeinone

Codeine	All salts of the above derivatives of codeine and all salts of codeine obtained by combining it or any of the above derivatives with any acid	
	Eucodin	Codeine methyl bromide
Heroin	All salts of heroin obtained by combining heroin with any acid	
Isonipecaine	Demerol	
Morphine	Dilaudid	Dihydromorphinone
	Ethylmorphine	
	Paramorphan	Dihydromorphine
	All salts of morphine and the above morphine derivatives formed by combining said substances with any acid	
Opium	Extract of opium, fluid extract of opium, tincture of opium	
Paraldehyde	Metaldehyde	
Sulphonmethane	Sulphonethymethane	2,2-diethylsulphonylbutane
	Sulphonthylmethane methane	3,3-diethylsulphonylpentane

49:4.0270 Quantity expression, unit form

If the drug is in tablet, capsule, ampule, or other unit form, the statement of the quantity or proportion of the substance of 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.

49:4.0280 Habit-forming drugs, labeling, and warning statement

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.

49:4.0290 Habit-forming drugs, prescription required

Drugs designated by the Louisiana Department of Health and Hospitals 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. 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.

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 whose label bears the caution legend that such drug is only to be sold on a prescription basis.

49:4.0300 Habit-forming drugs, labeling exemptions

A drugs shall not be considered to be misbranded by reason on failure of its label to bear the statement "Warning—May Be Habit-Forming"

(1) if such drug is not suitable for internal use, and it 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% 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%, and such drug contains one or more other active ingredients and is for parenteral use only.

49:4.0310 Misbranding, ingredient designation

A drug shall be deemed to be misbranded if its 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 the case that 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, and also including, whether active or not, the name, quantity, and proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein—provided, that to the extent that compliance with the requirements of this clause is impractical, exemptions shall be provided by 4.0450.

49:4.0320 Prescription drugs list

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:

Drug name	Drug name
Acetanilid[1]	Phosphides
Acetophenetidin[2]	Phosphorus
Aconite[3]	Radium and radioactive drugs
Aminopyrine	Squill
Antipyrine[2]	Strophanthus
Barbiturates	Strychnine[8]
Benzedrine sulphate[3]	Sulphanilamide
Bromides[4]	Sulphapyradine and other sulpha-drugs
Bromide-Aceteanilid combinations[5]	Sulphathiazole[3]
Cantharides[3]	Tansy, Tansy Oil
Causaline sedormide	Thiocyanates
Chrysarobin or goa powder	Thyroid
Chrysophanic acid	Antihelminthics, including carbon tetrachloride, tetrachloroethylene, male fern (aspidium), santonin, wormseed oil (chenopodium oil), and thymol
Cincophen, Neocinopene and other cincophen derivatives	
Colchicine	
Colchicum	
Digitalis	
Emetine	
Epinephrine[6]	
Ipecac[7]	

[1] where dosage provides a total daily intake of more than 5 grains or more than 2.5 grains in a 3-hour period
[2] where dosage provides a total daily intake of more than 15 grains
[3] for internal use
[4] where dosage provides a total daily intake of more than 30 grains or more than 15 grains in a 3-hour period
[5] where dosage provides a total daily intake of more than 15 grains of sodium bromide and 5 grains of acetanilid or more than 7.5 grains of sodium bromide and 2.5 grains of acetanilid in a 3-hour period
[6] in a 1% or stronger solution
[7] where dosage provides a total daily intake of more than 10 grains
[8] where dosage provides a total daily intake of more than 1/20 of a grain

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.

49:4.0330 "Dispense" defined

The term “dispense” as used in 4.0320 shall mean the use of a drug as an ingredient in the compounding of any prescription issued by a physician, dentist or veterinarian in his professional practice.

49:4.0340 Physician, dentist, and veterinarian must be licensed

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 drugs or devices.

49:4.0350 Specific names required

The name of an ingredient, substance, derivative, or preparation required by 4.0310 to be borne on the label of a drug shall be the name thereof which is listed in 4.0310, 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 it in the compendium, the ingredient may be designated on the label of the drug by the common or usual name in the compendium.

49:4.0360 Quantities required

Where a component of a drug contains a substance the quantity or proportion of which is required by 4.0310(2) to appear on the label and the component is not a derivative or preparation of that substance, as defined in 4.0380, 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 4.0310(2) to appear on the label.

49:4.0370 Abbreviations and chemical formulae not common or usual names

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”; “aminopyrine” the same as “amidopyrine”. The name “alcohol” without qualification shall mean “ethyl alcohol.”

49:4.0380 Misbranding, ingredients, derivatives designation

A derivative or preparation of a substance named in 4.0310(2) is an article which is an article which is derived or prepared from such substance by any method.

49:4.0390 Misbranding, ingredients or derivatives

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 in 4.0310(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.

49:4.0400 Labeling, weight, or measure of a drug

If the drug is in tablet, capsule, ampule, 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 of the drug. Such a statement shall be in terms which are informative to the ordinary consumer and user of the drug.

49:4.0410 Alcohol and other ingredient labeling

A statement of the proportion of alcohol present shall express the percentage of absolute alcohol by volume at 60°F (15.56°C). 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°F (20°C), but in such case the statement shall be so qualified as to show definitely that the proportion is expressed by volume.

49:4.0420 Statement of quantity or proportion of a derivative or preparation

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, then the quantity or proportion of such substance shall also be stated on the label of the drug.

49:4.0430 Misleading labeling

A label of a drug may be deemed to be misleading by reason (among other reasons) of:

(1) the order in which the names of the 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.

49:4.0440 Labeling—exemption from requirements, conditions for exemption

The label of a drug shall be exempt from compliance with the requirements of 4.0310(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 so as to comply with the requirements of R.S. 40: 617(4) and regulations 4.0200 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 4.0190 under R.S. 40: 617(3) and this omission will allow sufficient space to include the information required by 4.0310(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 4.0310(2) shall be stated as prominently as is practicable.

49:4.0450 Labeling—exemption of certain alkaloids, conditions of exemption

A drug shall be exempt from the requirements of 4.0310(2) with respect to the alkaloids, atropine, hyoscine or hyoscyamine, contained in the drug, if the alkaloid is contained therein as a constituent of belladonna, hysocyamus, 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.

49:4.0460 Drug labeling—directions, warnings

The labeling of drugs or devices shall bear:

(1) adequate directions for use; or

(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.

49:4.0470 Labeling—Inadequate directions

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 or 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
(6) preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

49:4.0480 Labeling of drugs or devices—exemptions from requirements

A shipment or other delivery of a drug or device shall be exempt from the requirements of 4.0460(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, 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 practices) bears the statements: "Caution—to be dispensed only by a _____", the blank being filled in with one or more of the words "physician", "dentist", or "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 as follows:
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.

49:4.0490 Labeling exemptions

A shipment or other delivery of a drug or device shall also be exempt from the requirements of 4.0460(1) if it complies with all the conditions set forth in paragraphs 4.0480(3) and (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.

49:4.0500 Labeling exemptions, for manufacturing use only

A shipment or other delivery of a drug or device shall also be exempt from the requirements of 4.0460(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."

49:4.0510 Labeling exemptions, common uses

A shipment or other delivery of a drug or device shall also be exempt from the requirements of 4.0460(1) with respect to common uses, adequate directions for which are known by the ordinary individual.

49:4.0520 Labeling exemptions void

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 membranes.

(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.

49:4.0530 Expiration of labeling exemption

Any exemption of a drug or device under 4.0480, 4.0490, or 4.0500 shall 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 4.0460(1) of these regulations.

49:4.0540 Labeling exemption, drugs to be processed, labeled, or repacked

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 where originally processed or packed, shall be exempt, except as provided by 4.0550 and 4.0560, from compliance with the labeling and packaging requirements of R.S. 40: 616(5), R.S. 40: 617 (3,5,6,7), and 4.0460 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, packed, or relabeled; 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 insure 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 has 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.

49:4.0550 Voiding of exemption under clause (1) of 4.0540

Any exemption of a drug or device under Clause (1) of 4.0540 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.

49:4.0560 Voiding of exemption under clause (2) of 4.0540

Any exemption of a drug or device under Clause (2) of 4.0540 shall immediately become void:

(1) upon refusal by the person responsible for the shipment of delivery of the drug or device to make available for inspection a copy of the written agreement specified in and required by 4.0540(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 4.0540(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.

49:4.0570 Use of harmless animal or vegetable dyes, coal-tar colors

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 the purposes of coloring only in drugs, drug products, drug ingredients, or their containers.