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

BASIC REQUIREMENTS FOR PROSPECTIVE COSMETIC MANUFACTURERS

(Revised 3/8/10)

A. GENERAL INFORMATION.

1. **Permits**: 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

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. According to the Food and Drug Administration, cosmetics manufacturers are not required to register their firms or have ingredients or finished products approved prior to marketing. The following quote is taken from

http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074162.htm (cited 3/8/10):

> *Manufacturers are not required to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries to FDA. However, companies are encouraged to register their establishments and file Cosmetic Product Ingredient Statements with FDA's Voluntary Cosmetic Registration Program (VCRP).*

C. RELEVANT STATUTES/REGULATIONS. Attached are the following rules and regulations pertaining to the manufacture of drugs in the state of Louisiana:

- ► Louisiana State, Food, Drug, and Cosmetic Law (LSA R.S. 40: §601 *et seq*)
- ► Louisiana State Food, Drug, and Cosmetic Regulations, Cosmetic Regulations (49:5.0000-49:5.0290)

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

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

COSMETIC REGULATIONS

49:5.0000 Labeling—cautionary statements, coal-tar dyes

A hair dye shall not be deemed in violation of Section R.S. 40:601(1) and (5) if it contains a coal-tar dye or intermediate and its label bears the following legend conspicuously displayed thereon: "Caution—this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness" and the labeling of which bears adequate directions for such preliminary testing.

49:5.0010 Coal-tar hair dyes—coal-tar colors or intermediates

The term "coal-tar hair dye" includes all articles containing any coal tar color or intermediate, which color or intermediate alters the color of the hair when applied to the hair under conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

49:5.0020 Eyelash and eyebrow dyes—exclusion from hair dye

The term "hair dye" shall not include eyelash dyes or eyebrow dyes.

49:5.0030 Misbranding of cosmetics

A cosmetic shall be deemed misbranded if any representation in the labeling is false or misleading with respect to another cosmetic, or a food, drug, or device.

49:5.0040 Misleading cosmetic labeling

The labeling of a cosmetic which contains two or more ingredients may be deemed misleading by reason (among other reasons) of the designation of such cosmetic by a name which includes or suggests the name of one or more but not all of the ingredients, even though the names of all the ingredients are stated elsewhere in the labeling.

49:5.0050 Misbranding, firm on label not the actual manufacturer

When a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with the cosmetic, such as "Manufactured for and Packed by _____ ", "Distributed by _____", or other similar phrase which expresses the facts. Where the name of the actual manufacturer or packer does not appear on the label, this information shall be furnished to the department upon request.

49:5.0060 Misbranding, business address

The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

49:5.0070 Misbranding, principal place of business

Where a person manufactures, packs, sells, or distributes a cosmetic 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 cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

49:5.0080 Labeling, not misleading in any particular

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

49:5.0090 Labeling, quantity of contents

The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic.

49:5.0100 Labeling, quantity of contents, accurate information

The statement of the quantity of the contents shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or

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

49:5.0110 Quantity of contents, units of measure, export shipments

A statement of the quantity of contents by weight shall be in terms of avoirdupois pound and ounce. A statement of the quantity of contents by liquid measure shall be in terms of the United States gallon of 231 cubic inches an of the quart, pint, and fluid ounce subdivisions thereof, and shall express the volume at 68°F (20°C). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is transported.

49:5.0120 Quantity of contents, metric system supplement

A statement of weight or measure in the terms specified in 5.0110 may be supplemented by a statement in terms of the metric system of weight or measure.

49:5.0130 Quantity of contents, accurate information

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

49:5.0140 Quantity of contents, fractions, common and decimal

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

49:5.0150 Quantity of contents, expression of largest package units

If the quantity of the cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in 5.0110, and which is applicable to such cosmetic under the provisions of 5.0100, the statement shall express the largest of such units contained in the package; for example, the statement on the label of the package which contains one pint of cosmetic shall be “1 pint” and not “16 fluid ounces”, unless the statement is made in accordance with the provisions of 5.0160. Where a 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 5.0110; for example, 1 ¾ quarts may be

expressed as “1 quart 1 ½ pints” or “1 quart 1 pint 8 fluid ounces”; “1 ¼ pounds” may be expressed as “1 pound 4 ounces.” The stated number of any unit which is smaller than the largest unit (specified in 5.0110) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified; for example, instead of “1 quart 16 fluid ounces” the statement shall be “1 ½ quarts” or “1 quart 1 pint”; instead of “24 ounces” the statement shall be “1 ½ pounds” or “1 pound 8 ounces.”

49:5.0160 Quantity of contents, fractions of units

In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

49:5.0170 Quantity of contents—minimum, average quantity

The statement of the quantity of contents shall express the minimum quantity, or the average quantity, of the contents of the package. 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.

49:5.0180 Quantity of contents—variations below or above minimum

where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variation below the stated minimum weight or measure caused by ordinary and customary exposure, after the cosmetic is received from interstate 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.

49:5.0190 Quantity of contents—variations permitted

Where the statement does not express the minimum quantity, variation shall be permitted:

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

(2) when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice. But variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or any other delivery of the cosmetic 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.

49:5.0200 Quantity of contents—variations determined by facts

The extent of variations from the stated quantity of the contents permissible under 5.0180 and 5.0190 shall be determined by the facts in the case of each individual shipment or other delivery.

49:5.0210 Quantity of contents—exemptions from requirements

A cosmetic shall be exempt from compliance with the requirements of an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of 5.0100, is less than ¼-ounce avoirdupois, or less than 1/8-fluid ounce, or (in case the units of the cosmetic can be easily counted without opening the package) less than six units.

49:5.0220 Quantity of contents—lack of prominence and conspicuousness

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 R.S. 40:622(3) by reason (among other reasons) of:

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

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

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

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

(5) insufficiency of label space (for the prominent placing of the 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.

49:5.0230 Labeling—use of English 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 English language.

49:5.0240 Labeling—use of foreign language

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.

49:5.0250 Labeling—exemptions from requirements

A cosmetic which is to be labeled, processed, or repacked in substantial quantities in accordance with regular trade practice at an establishment other than that were originally processed or packed, shall be exempt except as provided by 5.0260 and 5.0270, from compliance with the labeling requirements of R.S. 40:621(1) and R.S. 40:621(2) 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 cosmetic is the operator of the establishment where the cosmetic is to be processed, labeled, or repacked; or

(2) in case such person is not the operator, the shipment or delivery of the cosmetic is made under a written agreement, signed by and containing the post office addresses of the person responsible for the shipment or delivery and the operator of the labeling, processing, or repacking plant; and also containing specifications for the labeling, processing, or repacking, as the case may be, which, if followed, will ensure that the cosmetic will not be adulterated or misbranded within the meaning of the Act upon completion of the labeling, processing, or repacking. Each party to the agreement shall keep a copy of the agreement until every component of the shipment or delivery covered by the agreement has been removed from the labeling, processing or repacking establishment; and copies of the agreement shall be made available for inspection at any reasonable hour to any officer or employee of the department.

49:5.0260 Labeling—voiding of labeling exemptions, adulteration or misbranding

An exemption of a shipment or other delivery of a cosmetic under 5.0250(1) shall immediately become void if the cosmetic or any part thereof at the time of removal from the original establishment is adulterated or misbranded within the meaning of the Act.

49:5.0270 Labeling—immediate voiding of exemptions

An exemption of a cosmetic under 5.0250(2) shall immediately become void:

(1) upon refusal by the person responsible for the shipment or delivery of the cosmetic to make available for inspection a copy of the agreement specified in and required by 5.0250(2).

(2) upon refusal of the operator of the establishment where the cosmetic is to be labeled, processed, or repacked to make available for inspection a copy of the agreement specified in and required by 5.0250(2).
(3) if the cosmetic or any part thereof at the time of removal from the original establishment is adulterated or misbranded within the meaning of the Act.

49:5.0280 Use of animal and vegetable dyes, U.S. certified coal-tar colors

Only harmless animal or vegetable dyes and such coal-tar colors as have been certified by the federal Food and Drug Administration under authority of the federal Food, Drug, and Cosmetic Act of 1938 and defined under coal-tar color regulations as published by the Federal Security Agency in Services and Regulatory Announcement F.D.C. 3, issued September 1940, or as amended from time to time, shall be used in, offered for sale for use in, or distributed for use in or on any cosmetic or cosmetic products.

The following regulation was adopted by the Louisiana department on July 12, 1946, officially promulgated, and became effective August 6, 1946.

49:5.0290 Estrogenic hormones—prohibition of use

No cosmetic or beauty preparation containing as one of its ingredients estrogenic hormones, any of their chemical derivatives, or any synthetic chemical product possessing properties similar to those of estrogenic hormones may be manufactured, processed, packed, sold, or distributed in Louisiana unless

(A) its label bears adequate directions for use; and
(B) its label bears the number of international units per ounce of each such ingredient