RULE

Department of Health
Office of Public Health

Registration of Foods, Drugs,
Cosmetics and Prophylactic Devices
(LAC 49:I.Chapter 5 and LAC 51:VI.301)

Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, the state health officer, acting through the Louisiana Department of Health, Office of Public Health (LDH-OPH), has amended certain sections of Chapter 5 (Registration of Foods, Drugs, Cosmetics and Prophylactic Devices) of Title 49 (Public Health—Food, Drugs, and Cosmetics) and Section 301 of Part VI (Manufacturing, Processing, Packing and Holding of Food, Drugs, and Cosmetics) of Title 51 (Public Health-Sanitary Code) of the Louisiana Administrative Code. This Rule implements a regulatory framework for industrial hemp-derived cannabidiol products (IHDCP) in accordance with directives of Subsection J of Section 1382 of Title 3 of the Revised Statutes of 1950, enacted as part of Act 164 of the 2019 Louisiana Legislature.

For the reason set forth above, the following additions and amendments to LAC 49 and 51 are hereby adopted. This Rule is hereby adopted on the day of promulgation.

Title 49
PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS
Part I. Regulations
Chapter 5. Registration of Foods, Drugs, Cosmetics and Prophylactic Devices

§501. Definitions
[Formerly 49:2.2100]

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

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

* * *

Cannabidiol—a nonpsychotropic cannabinoid found in *Cannabis sativa* L. and other conspecifics that can have a variety of physiological effects on the human body.

CBD—cannabidiol.

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

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

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

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

* * *

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

* * *

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

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

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

Industrial Hemp-Derived Cannabidiol Products (IHDCP)—any product intended for human use and containing cannabidiol that was made from industrial hemp.

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

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

* * *

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

Registration Fee—examination and investigation fee.

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THC—delta-9 tetrahydrocannabinol.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Louisiana State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020).

§503. Registration Provisions
[Formerly 49:2.2110]

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by Louisiana State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020).

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

A. In accordance with the provisions of R.S. 40:627 and 628 and in order to establish revised procedures for the annual registration of products, manufacturers, packers,

processors and distributors of all processed foods, proprietary or patent medicines, prophylactic devices and cosmetics in packaged form, whose names appear on the labels, must submit an application for registration of such products on or before July 1 of each year. Certificates of registration will be issued to each firm for a period of one year expiring on June 30 of each year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

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

§511. Late Registration Penalty Fees [Formerly 49:2.2150]

Repealed.

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

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

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

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

B. …

* * *

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

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

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

§517. Registration of Industrial Hemp-Derived Cannabidiol Products

A. In accordance with the provisions of R.S. 3:1482 as promulgated by the 2019 Legislature, manufacturers or distributors of industrial hemp-derived cannabidiol products must register each separate and distinct product with the department-annually and initially within 90 days of the effective date of these regulations or prior to marketing the products in the state of Louisiana, whichever comes first.

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

C. In lieu of the annual examination and administration charge normally collected under R.S. 40:628(B), the applicant for an industrial hemp-derived cannabidiol product registration must provide (both initially and on or before July 1 of each year) the department with an application form, a cashier's check or money order made payable to the department in the amount of $50 per each separate and distinct CBD product, specimen copies of labeling in paper or electronic format, and a list of all products the applicant wishes to register with the department. If the packet meets these regulatory requirements, the department will issue to the applicant an FD-8a Certificate of IHDCP (Industrial Hemp-Derived Cannabidiol Products) Registration and the application information will be entered into the Industrial Hemp-Derived Cannabidiol Products Database.

D. No person is authorized to distribute any industrial hemp-derived cannabidiol products in the state of Louisiana unless that person has first obtained a Certificate of IHDCP Registration from the department.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020).

§519. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Certificate of Analysis

A. In addition to the requirements enumerated in R.S. 40:608, industrial hemp-derived cannabidiol products must bear labeling that includes a scannable bar code, QR code, or a web address linked to a document or website containing the certificate of analysis for that product.

B. The certificate of analysis must be from a laboratory that is accredited by LDH/OPH.

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

1. the batch number of the product;
2. the date the batch was received by the laboratory;
3. the date the testing was completed;
4. the laboratory methodology used for each analysis referenced in the report;
5. the amount of THC by dry weight in milligrams;
6. the amount of CBD by dry weight in milligrams;
7. the amount of any detected residual solvent in the product in parts per million;
8. the amount of any detected pesticide residues in the product in parts per million;
9. the amount of any microbiological contaminants in the product in appropriate units; and
10. the amount of any detected heavy metal traces in the product in parts per million.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020).

§521. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Disclaimer

A. Each primary container of industrial hemp-derived cannabidiol product must bear the following statement: "This product has not been evaluated by the Food and Drug

Administration and is not intended to diagnose, treat, cure, or prevent any disease."

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020).

§523. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Medical Claims Prohibited

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

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

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

§525. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Dietary Supplements Prohibited

A. No industrial hemp-derived cannabidiol product may be marketed as a dietary supplement.

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

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

§527. Penalties for Violations of Requirements to Register Industrial Hemp-Derived Cannabidiol Products

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

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

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

§529. Exemptions

A. Industrial hemp-derived cannabidiol products that have been produced in accordance with R.S. 40: 1046 or that are Food and Drug Administration (FDA)-approved pharmaceuticals are not subject to the requirements of this regulation.

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

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

Title 51
Public Health—Sanitary Code
Part VI. Manufacturing, Processing, Packing and Holding of Food, Drugs and Cosmetics

Chapter 3. Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding Human Food

§301. General Provisions; Code of Federal Regulations [formerly paragraph 6:039]

A. The Criteria in 21 CFR 117 Subpart A, Subpart B and Subpart F (Code of Federal Regulations) shall apply in determining whether the facilities, methods, practices, and controls used in the manufacturing, processing, packing or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed and held under sanitary conditions.

B. In accordance with R.S. 3:1468, facilities producing industrial hemp-derived cannabidiol products intended for human consumption will be inspected under the provisions of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq., and R.S. 3:1482(J).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1234 (June 2002), amended by the Department of Health, Office of Public Health, LR 46:360 (March 2020).

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and
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2000#034

RULE

Department of Insurance
Office of the Commissioner

Regulation 63—Prohibitions on the Use of Medical Information and Genetic Test Results
(LAC 37:XIII.Chapter 45)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950, et seq., has amended Regulation 63-Prohibitions on the Use of Medical Information and Genetic Test Results.

The regulation has been amended to comport with current law regarding the use of medical information, including pregnancy tests, genetic tests and related genetic test information, through the passage of Acts 2003, No. 129, §1, Acts 2004, No. 325, §1, Acts 2009, No. 419, §1, Acts 2010, No. 919, §1, and Acts 2016, No. 58, §1 of the Regular Sessions of the Louisiana Legislature. This Rule is hereby adopted on the day of promulgation.

Title 37
INSURANCE
Part XIII. Regulations

Chapter 45. Regulation 63—Prohibitions on the Use of Medical Information and Genetic Test Results

§4503. Authority

A. This regulation is issued pursuant to the authority vested in the Commissioner of Insurance under R.S. 22:11, 22:971, 22:258, 22:242(7), 22:1964(22) and (23), 22:1022, and 22:1023 of the *Insurance Code*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, 22:971, 22:258, 22:242(7), 22:1964(22) and (23), 22:1022, and 22:1023 of the *Insurance Code*.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Commissioner of Insurance, LR 24:1120 (June 1998), amended LR 46:360 (March 2020).