John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

To: **The Honorable John Bell Edwards, Governor, State of Louisiana** (Via Hand Delivery)
The Honorable Jeff Landry, Attorney General, Louisiana Department of Justice (Via Hand Delivery)
The Honorable John A. Alario, Jr., President, Louisiana Senate (apa.senatepresident@legis.la.gov)
The Honorable Taylor F. Barras, Speaker, Louisiana House of Representatives (apa.housespeaker@legis.la.gov)
Catherine Brindley, Editor, *Louisiana Register* (reg.submission@la.gov)
Senate Health and Welfare Committee (apa.s-h&w@legis.la.gov)
House Health and Welfare Committee (apa.h-hw@legis.la.gov)

From: **Rebekah E. Gee MD, MPH, Secretary, Louisiana Department of Health**

Date: **July 10, 2019**

Re: **Justification of Promulgation of Emergency Rule**
LAC 49:501, 503, 509, 511, 515, 517, 519, 521, 523, 525, 527, 529 and LAC 51.VI.301 - Registration of Foods, Drugs, Cosmetics and Prophylactic Devices

MEMORANDUM

In accordance with the Administrative Procedure Act (La. R.S. 40: 950 *et seq.*) as amended, the Louisiana Department of Health, Office of Public Health, is submitting the following emergency rule that amends LAC 49:501, 503, 509, 511, 515, 517, 519, 521, 523, 525, 527, 529 and LAC 51.VI.301.

This action is being taken as authorized by R.S. 40:4(A)(13) under the mandate of Act 164 of the 2019 Louisiana Legislature. The changes will authorize the LDH/OPH the ability to properly register these items, inspect firms that manufacture such items for human consumption, and conduct oversight of labelling, which could affect the health of Louisiana's citizens and visitors. Further, this Emergency Rule will provide the state health officer the ability to make critical decisions that protect human health.

Should you have any questions or require additional information regarding this matter, please do not hesitate to contact Michael Vidrine at Michael.Vidrine@la.gov or (225) 342-7542.

Attachments: Emergency Rule – LAC 49:501, 503, 509, 511, 515, 517, 519, 521, 523, 525, 527, 529 and LAC 51.VI.301

Cc: Jimmy Guidry, MD, State Health Officer
Alexander Billioux, MD, DPhil, Assistant Secretary, OPH
Michael Vidrine, Bureau of Sanitarian Services, OPH
Anita Dupuy, Legislative Liaison, LDH
Allen Enger, Acting Rulemaking Coordinator, LDH
Catherine Brindley, *Louisiana Register* Editor, Office of the State Register

DECLARATION OF EMERGENCY

Louisiana Department of Health
Office of Public Health

Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices
LAC 49:501, 503, 509, 511, 515, 517, 519, 521, 523, 525, 527, 529 and LAC 51.VI.301

The Louisiana Department of Health, Office of Public Health (LDH/OPH), pursuant to the emergency rulemaking authority granted by R.S. 40:4(A)(13), hereby adopts the following Emergency Rule for the protection of public health. This Emergency Rule is promulgated specifically in accordance with R.S. 49:953(B) of the Administrative Procedure Act (R.S. 49:950, *et seq.*).

The LDH/OPH finds it necessary to make changes to the Louisiana Administrative Code given the need for regulation of the cannabidiol-containing products made legal for sale to consumers under the provisions of Act No. 164 of the 2019 Louisiana Legislature. The following changes will authorize the LDH/OPH the ability to properly register these items, inspect firms that manufacture such items for human consumption, and conduct oversight of labelling, which could affect the health of Louisiana's citizens and visitors. Further, this Emergency Rule will provide the state health officer the ability to make critical decisions that protect human health. Accordingly, the following Emergency Rule, effective upon signature, shall remain in effect for a maximum of 120 days, or until the final Rule is promulgated, whichever occurs first.

This rule amends §501, §503, §509, and §515, repeals §511, and adds new §§517-529 of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics. Changes to §501 amend typographical errors in the original language and add new definitions. Changes to §503 reflect changes to the name of the unit and the agency since the promulgation of the original language. Changes to §509 reflect the schedule actually being followed for registrations, which matches with the state's fiscal year (July 1 – June 30). Changes to §515 address the deletion of date language for February 1, 1986. §511 referenced a delinquent penalty schedule no longer in use or authorized by state law. §§517-529 are the new industrial-hemp-derived cannabidiol product registration rules.

Additionally, this rule amends §301 of Chapter 3 of Part VI of Title 51—Public Health—Sanitary Code. Changes to §301 update an adoption-by-reference of federal regulations and add a new rule regarding the inspection of manufacturers of cannabidiol-containing products for human consumption.

Title 49

PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS

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).

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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 Food and Drug/Milk and Dairy Unit ~~of LDH/OPH~~ attesting that products produced or distributed by the holder's company have been registered with that entity.

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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.

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~~*W*~~*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 consumption 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 Food and Drug/Milk and Dairy Unit of LDH/OPH that fall into the category of industrial-hemp-derived cannabidiol products.

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QR Code—Quick Response Code, a type of machine-readable, two-dimensional barcode that stores information about a product.

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THC—delta-9 tetrahydrocannabinol.

AUTHORITY NOTE: Promulgated in accordance with ~~Louisiana Revised Statutes of 1950, Title 40, as amended~~R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resources, Office of Preventive and Public Health Services~~Louisiana State Board of Health, September 1968~~.~~, amended by the Louisiana Department of Health, Office of Public Health, LR 45:

§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 Louisiana Food and Drug ~~Unit~~/Milk and Dairy Unit/ ~~OPH/DHH~~LDH/OPH.

AUTHORITY NOTE: Promulgated in accordance with ~~Louisiana Revised Statutes of 1950, Title 40, as amended~~R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resources, Office of Preventive and Public Health Services~~Louisiana State Board of Health, September 1968~~.~~, amended by the Louisiana Department of Health, Office of Public Health, LR 45:

§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 ~~August 1~~July 1 of each year. Certificates of registration will be issued to each firm for a period of one year expiring on ~~July 31~~ June 30 of each year. ~~The staggering of expiration dates of certificates will be discontinued and consolidated into one expiration date (July 31). The four registration categories, as established by previous rule of January 20, 1984, will be eliminated thus placing all firms into the same registration period of August 1 thru July 31 of the following year. The current expiration dates for the four registration categories are as follows.~~

~~Category 1~~	~~January 31~~
~~Category 2~~	~~April 30~~
~~Category 3~~	~~July 31~~
~~Category 4~~	~~October 31~~

~~B. In order to implement a smooth transition from staggered expiration dates to one annual expiration date, the Food and Drug Control Unit shall extend the expiration dates of the current registration certificates from each registration category, excluding category 3, to the July 31, 1986 expiration date. Thus, certificates of registration for categories 1, 2, and 4 expiring on January 31 and April 30, 1986, and October 30, 1985, respectively, will automatically be extended until July~~

~~31, 1986. For the purposes of avoiding confusion on the part of industry with respect to the filing of correct registration fees, the Food and Drug Control Unit shall waive the submission of applications for registration and registration fees for those firms in categories I, 2, and 4 which would otherwise be prorated over periods of three, six and nine months.~~

~~C. This rule will allow a smooth transition into the revised registration fee schedule as provided by Act 344 of the 1985 Legislative Session which amended R.S. 40:627(D) of the Food and Drug Law. The new fee schedule is effective as of February I, 1986; however, the new fees will not be collected until August I, 1986. Registration fees as provided by the amended law are as follows.~~

~~1. Each manufacturer, packer, or proprietor shall be assessed an annual expiration and investigation charge of not more than $10 for any one separate and distinct product registered, up to a maximum of $100.~~

~~2. Registration fees for products will be assessed as outlined in the following schedule.~~

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

~~D. Notification of renewal of certificates and revised examination and Investigation Fee schedules will be made known to certificate holders in categories 1, 2, and 4 by way of a letter to each firm announcing the proposed changes in fees and extension of certificates. Certificates of category 3 firms will not be affected in that certificates in that category currently expire on July 31 of each year.~~

AUTHORITY NOTE: Promulgated in accordance with ~~Louisiana Revised Statutes of 1950, Title 40, as amended~~R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resources, Office of Preventive and Public Health Services~~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 Louisiana Department of Health, Office of Public Health, LR 45:.

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

~~A. The late registration penalty fees as required by R.S. 40:627(D) will be revised effective February 1, 1986, in accordance with Act 344 of the 1985 Legislature. Late registration penalty fees currently assessed are $100 per product with a maximum penalty fee of $500 for any one firm during the calendar year.~~

~~B. Thus, late penalty fees are currently as follows.~~

~~Number of Products~~	~~Penalty Fee~~
~~1~~	~~$100~~
~~2~~	~~$200~~
~~3~~	~~$300~~
~~4~~	~~$400~~
~~5~~	~~$500~~
~~More than 5~~	~~$500~~

~~C. The revised penalty fees for late registration will be subject to implementation effective February 1, 1986, but assessment of the fees will not be initiated in that the current certificates will automatically be extended by this proposed rule.~~

AUTHORITY NOTE: Promulgated in accordance with ~~Louisiana Revised Statutes of 1950, Title 40, as amended~~ R.S. 40:4(A)(13), 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 Louisiana Department of Health, Office of Public Health, LR 45:

§515. Late Registration 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~~, effective February 1, 1986,~~ 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~~, effective February 1, 1986,~~ will be imposed on those firms which fail to submit an application for registration and registration fees on or before ~~August 1~~ July 1 of each year. ~~However, a grace period of 45 days will be given to all firms extending the deadline for receipt of applications and fees to September 15 of each year. A final notice reminder letter will be sent to all firms on or about September 1 of each year thus serving notice to firms 15 days prior to implementing penalty fees denoted above.~~

AUTHORITY NOTE: Promulgated in accordance with ~~Louisiana Revised Statutes of 1950, Title 40, as amended~~ R.S. 40:4(A)(13), 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~~ 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 Louisiana Department of Health, Office of Public Health, LR 45:

§517. Registration of Industrial-Hemp-Derived Cannabidiol Products

A. In accordance with the provisions of R.S. 3:1470 as promulgated by the 2019 Legislature, manufacturers or distributors of industrial-hemp-derived cannabidiol products must register each separate and distinct product with the Food and Drug/Milk and Dairy Unit of LDH/OPH 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 Food and Drug/Milk and Dairy Unit of LDH/OPH 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 Database) Registration and the application information will be entered into the LDH/OPH 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 Food and Drug/Milk and Dairy Unit.

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

§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 colony-forming units (CFU) per gram; 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), 40:4(A)(13), and R.S. 40:604.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

§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), 40:4(A)(13), and R.S. 40:604.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

§523. Industrial-Hemp-Derived Cannabidiol Products Labeling Requirements: Health 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 health claims.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), and R.S. 40:604.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

§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), R.S. 40:4(A)(13), and R.S. 40:604.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

§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), R.S. 40:4(A)(13), and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

§529. Exemptions

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), and R.S. 40:604.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 45:

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 ~~C~~criteria in 21 CFR ~~110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.93~~ 117 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. 3:1468.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1234 (June 2002)~~.~~, amended by the Louisiana Department of Health, Office of Public Health, LR 45:

Interested persons may submit written comments to Michael Vidrine, Director, Sanitarian Services, Office of Public Health, Louisiana Department of Health, P.O. Box 4489, Baton Rouge, LA 70821-4489. He is responsible for responding to inquiries regarding this Emergency Rule.

Signed on the 10th day of July, 2019, by:

Jimmy Guidry, MD, State Health Officer

Rebekah E. Gee, MD, MPH, Secretary

PROVIDER IMPACT STATEMENT

TITLE 49

PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS

CHAPTER 5. REGISTRATION OF FOODS, DRUGS, COSMETICS AND PROPHYLACTIC DEVICES

AND

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

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of 2014 Regular Legislative Session. Per HCR 170, "provider" means an organization that provides services for individuals with developmental disabilities. In particular, there should be no known or foreseeable effect on the:

1. Effect on the staffing level requirements or qualifications required to provide the same level of service;
2. Total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. Overall effect on the ability of the provider to provide the same level of service.