**RULE**

**Louisiana Department of Health**

**Office of Public Health**

Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices

LAC 49:501, 517, 519, 521, 523, 525, 527, 529

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, notice is hereby given that the secretary, acting through the Louisiana Department of Health, Office of Public Health (LDH/OPH), has recodified parts of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics and has amended those rules to comply with the requirements of Act 336 of the 2021 Regular Legislature.

 This rule amended §501 and §§517 – 525 of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics. §§527-529 are recodified with new requirement language and the original §§527- 529 are relocated to §§531 – 533. Changes to §501 amended existing definitions and added new definitions. Changes to §§517 - 533 reflect changes to the name of hemp-derived products regulated by the department as well as changes to the statutory requirements.

**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.

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

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

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

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

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*THC*~~⎯~~a combination of tetrahydrocannabinol and tetrahydrocannabinolic acid.

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

HISTORICAL NOTE: Promulgated by the Louisiana State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:479 (April 2021), LR 48:

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**§517. Registration of Consumable Hemp Products**

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

 B. . . .

 C. In lieu of the annual examination and administration charge normally collected under R.S. 40:628(B), the applicant for a consumable hemp product registration must remit to (both initially and on or before July 1 of each year) the department the amount of $50 per each separate and distinct product. The initial application packet will consist of the required remittance in a form deemed acceptable by the department, a completed application form, specimen copies of each product label in paper or electronic form, and a list of products the firm intends to register with the department. If the packet meets these regulatory requirements and the other requirements described in these regulations, the department will issue to the applicant an FD-8a Certificate of Consumable Hemp Product Registration and the application information will be entered into the Consumable Hemp Products Database.

 D. No person is authorized to distribute any consumable hemp products in the state of Louisiana unless that person has first obtained a Certificate of Consumable Hemp Product Registration from the department.

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

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

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

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

B. – C. . . .

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

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

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

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

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), LR 48:

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

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

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

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

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

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

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:360 (March 2020), amended LR 47:480 (April 2021), LR 48:

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

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

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

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:360 (March 2020), amended LR 47:480 (April 2021), LR 48:

**§531. Penalties for Violations of Requirements to Register Consumable Hemp Products**

1. Any person who violates the provisions requiring registration of consumable hemp products is subject to the penalties provided for by the State Food, Drug, and Cosmetic Law (R.S. 40:601, et seq.) or other sanctions provided for by R.S. 3:1484.

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

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

**§533. Exemptions**

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

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

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