DECLARATION OF EMERGENCY

Department of Health
Office of Public Health

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

The Louisiana Department of Health, Office of Public Health (LDH/OPH), pursuant to rulemaking authority granted by R.S. 3:1483(L), including the emergency rulemaking authority granted therein, and 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. 49:962 of the Administrative Procedure Act (R.S. 49:950, et seq.). This Emergency Rule expressly rescinds and replaces the Emergency Rule adopted by LDH/OPH on January 20, 2023.

The LDH/OPH finds it necessary to promulgate an Emergency Rule effective June 26, 2023. This Emergency Rule is necessary to prevent imminent peril to the public health, safety, or welfare and is also done pursuant to the express statutory authority granted by R.S. 3:1483(L). Current LDH/OPH rules in LAC 49 Chapter 5 concerning the registration of consumable hemp products do not explicitly prohibit the registration of products utilizing dosage vehicles designed or intended for other than oral consumption or topical use, or require that applicants submit any documentation concerning same. This Emergency Rule will provide LDH/OPH with explicit authority concerning dosage vehicles to: i) require proof that consumable hemp products for which registration is sought are not designed or intended for other than oral consumption or topical use, or to facilitate same, ii) deny requested registration of consumable hemp products that are designed or intended for other than oral consumption or topical use, or to facilitate same, and iii) authorize LDH/OPH to revoke the registration of consumable hemp products that are designed or intended for other than oral consumption or topical use, or to facilitate same.

This Emergency Rule also provides that a consumable hemp product packaged, labeled, or marketed in a manner that physically or functionally combines individual servings, resulting in a functional or suggested product serving size that exceeds eight milligrams of total THC per serving, shall not be registered and shall be subject to revocation of registration. The emergency rule also speaks specifically to the topic of "serving", and includes streamlined requirements for registration and registration renewal.

Accordingly, the following Emergency Rule, effective June 26, 2023, shall remain in effect for a maximum of 180 days, or until the final Rule is promulgated, whichever occurs first.

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]

* * *

E-Cigarette—a battery-operated device that is typically designed to resemble a traditional cigarette and is used to inhale a (usually nicotine-containing) vapor atomized by the device's heating element.

* * *

Vape Cartridge—the part of a vape pen containing the liquid to be inhaled by the user.

Vape Pen—a type of e-cigarette.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(L), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(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), LR 47:479 (April 2021), LR 48:1290 (May 2022), LR 49:

§517. Registration of Consumable Hemp Products

A. - 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 provide (both initially and on or before July 1 of each year) the department with a packet that includes:

1. a completed application form;
2. a cashier's check, money order, or electronic payment made payable to the department in the amount of $50 per each separate and distinct product;
3. specimen copies of labeling for each separate and distinct product in electronic format;
4. laboratory accreditation verification documentation;
5. laboratory certificate of analysis (COA) for each separate and distinct product;
6. attestation that the product was produced from hemp. However, the department reserves the right to request a copy of the current grower or processor's license issued by the authority of competent jurisdiction for the firm responsible for the hemp crop from which the products are derived;
7. for each separate and distinct product, photographs or renderings of the product that accurately depict the entirety of the product, including all accessories or physical items included or sold with the product, whether attached or not. The department may require the submission of a specimen of the actual product and all included accessories if it determines in its sole discretion that submitted renderings or photographs do not allow a sufficient determination that the product meets all applicable requirements of this Chapter; and
8. for each separate and distinct product, a detailed written description of how individual servings will be packaged and marketed for sale. A product whose label fails to comply with the requirements of §533 of this Chapter will not be registered. A product packaged, labeled, or marketed in a manner that physically or functionally combines individual servings, resulting in a functional or suggested product serving size that exceeds eight milligrams of total

THC per serving, shall not be registered and shall be subject to revocation of registration pursuant to §518 of this Chapter.

D. If all required packet contents, as set forth in Subsection C of this Section, are submitted and a product meets the applicable requirements of this Chapter and R.S. 3:1483, the department shall register the product by entering the application information into the consumable hemp products database. In instances of an annual renewal of a product, the department may allow for the applicant to attest/certify that the required information has not changed since the last application in lieu of repeat submission.

E. No person is authorized to distribute any consumable hemp product in the State of Louisiana unless such product is currently registered and entered into the consumable hemp products database by the department, except that if a firm submits product labeling and supporting documentation for review to the department and does not receive a written response within 15 business days of that initial submission, the product may be sold after the fifteenth business day by any permitted wholesaler or retailer until the submitting party receives notice in writing from the department that the product in question is accepted or rejected for registration. Upon the expiration of the 15 business days, the department will send written notice, via electronic mail only, confirming the "pending" status of any application and, if known, a date by which a final determination will be made.

F. Any firm may apply to the department for the designation of its products as "Louisiana Hemp Products," provided that those products are produced from hemp grown in Louisiana and are processed at a Louisiana-based manufacturer. These items shall be designated with a special mark on the department's list of registered products once they have been registered with the department.

G. No consumable hemp product shall be registered if one or more of the following conditions concerning dosage vehicles apply:

1. it is explicitly or clearly intended or characterized as being for inhalation, or to facilitate same; this prohibition shall not apply to hemp rolling papers;

2. it is explicitly or clearly intended or characterized as being for subcutaneous or transdermal use, or to facilitate same; this prohibition shall not apply to transdermal patches that are not designed for or capable of piercing the skin;

3. it is explicitly or clearly intended or characterized as being for intravenous or intramuscular infusion or injection, or to facilitate same;

4. it is explicitly or clearly intended or characterized as being for rectal or vaginal insertion, including, but not limited to, vaginal or anal suppositories; this prohibition shall not apply to products that are topical personal lubricants; or

5. it includes, is contained within, or constitutes a vape cartridge, vape pen, e-cigarette or a substantially similar item designed to facilitate inhalation.

H. Notice of final denial of a requested product registration shall state the specific reason(s) for the denial and shall include notice of right to an administrative hearing concerning same, which right shall expire unless the applicant files, in the manner specified therein, a written request for an administrative hearing with the department within 20 calendar days of receipt of the Notice. Any such request timely received shall be forwarded by the department to the Louisiana Division of Administrative Law. In addition to any method of service authorized by this Title, service of the Notice on the applicant may be effected through any means authorized by LAC 51.I:109. Additionally, service may be made by electronic mail sent to any email address provided by the registrant to the department as part of or subsequent to the permitting or registration process, and shall be deemed effective even if returned as undeliverable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), 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 47:479 (April 2021), LR 48:1290 (May 2022), LR 49:

§518. Revocation of a Consumable Hemp Product Registration

A. The department may revoke the registration of a consumable hemp product if:

1. any of the enumerated criteria set forth in §517.G. of this Chapter apply to the product;

2. any materials, including product information, specifications, photographs, or renderings, provided to the department in connection with the registration approval were erroneous or misleading, if non-erroneous or non-misleading materials would have resulted in denial of registration;

3. the product, including any accessories or physical items included therewith, is materially modified in a way that makes the photographs, renderings, or specimen submitted in connection with the registration no longer an accurate depiction thereof; or

4. the product, product label, product packaging, or product marketing violates any provision or requirement of this Chapter or R.S. 3:1483.

B. Revocation shall occur through issuance and service of an order revoking registration. The order shall state with specificity the nature of the violation(s), including citations to the provision(s) of this Chapter that have been violated. In addition to any method of service authorized by this Title, service on the registration holder may be effected through any means authorized by LAC 51.I:109. Additionally, service may be made by electronic mail sent to any email address provided by the registrant to the department as part of or subsequent to the registration process, and shall be deemed effective even if returned as undeliverable.

C. An order revoking registration shall include notice of right to an administrative hearing concerning same, which right shall expire unless the registrant files, in the manner specified therein, a written request for an administrative hearing with the department within 20 calendar days of receipt of the order. If such a written request is timely filed, then it shall be forwarded by the department to the Louisiana Division of Administrative Law. The order shall be stayed pending the decision of the Division of Administrative Law, subject to the provisions in Subsection D of this Section.

D. If the state health officer determines, in his sole discretion, that the product in question constitutes a nuisance dangerous to the public health or a danger to the public life, health, or safety, and includes that finding in the order revoking registration, the order shall be deemed an Emergency Order and shall not be stayed pending the decision of the Division of Administrative Law. Further, as of the effective date of this Emergency Rule, any registration of any product that, based on a determination by the department, in its sole discretion,

1. exceeds the THC limits set forth in R.S. Title 3, Chap. 10-a, Part VI, including, but not limited to, the milligrams per serving limit;

2. meets the criteria of §517.G.1 or §517.G.5 of this Chapter;

3. contains any type of cannabinoid that does not naturally occur in hemp; or

4. violates the criteria of §533 of this Chapter shall be deemed to meet the criteria for revocation under an Emergency Order.

E. This Section shall apply to any consumable hemp product registered with the department, regardless of registration date. This Section is expressly intended to apply to consumable hemp products registered both prior to and after June 26, 2023, the effective date of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), 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 47:479 (April 2021), LR 48:1290 (May 2022), LR 49:

§533. Consumable Hemp Products Labeling Requirements: Serving Sizes and THC Content

A. …

B. Serving sizes shall be delineated as follows:

1. for tinctures, extracts, concentrates, and other liquid-type products, there shall be an included measuring device capable of administering a single serving;

2. for beverages, the packaging must clearly enable a consumer to determine when a single serving has been consumed;

3. for all other products (e.g. tablets, capsules, cookies, gummies, etc.), an individual unit shall constitute a single serving and shall be separate and unattached to other units within a package. Thus, multiple servings shall not be combined and subject to scoring or separating in order to produce a single serving.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), 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 47:479 (April 2021), amended, LR 48:1290 (May 2022), amended, LR 49:

A representative of the LDH Cannabis Program, is responsible for responding to inquiries regarding this Emergency Rule, which may be sent to LACannabisProgram-hemp@la.gov.

Stephen Russo
Secretary

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