NOTICE OF INTENT
Louisiana 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), hereby amends the following Rule for the protection of public health. This Rule is promulgated specifically in accordance with R.S. 49:962 of the Administrative Procedure Act (R.S. 49:950, *et seq*.).

This proposed 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 La. 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 proposed 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 proposed 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 proposed Rule also speaks specifically to the topic of "serving", and includes streamlined requirements for registration and registration renewal.

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), amended LR 47:479 (April 2021), amended LR 48:1290 (May 2022), amended by the Department of Health, Office of Public Health, 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 51 LAC Part 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), amended LR 48:1290 (May 2022), amended LR 48:

§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 51 LAC Part 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, (i) 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, (ii) meets the criteria of §517.G.1 or §517.G.5 of this Chapter, (iii) contains any type of cannabinoid that does not naturally occur in hemp, or (iv) 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), amended, LR 48:1290 (May 2022), amended, 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 48:.

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;
2. the authority and rights of persons regarding the education and supervision of their children;
3. the functioning of the family;
4. family earnings and family budget;
5. the behavior and personal responsibility of children;
6. the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;

2. the effect on early childhood development and preschool through postsecondary education development;

3. the effect on employment and workforce development;

4. the effect on taxes and tax credits;

5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;

2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or

3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Monday, September 11, 2023 at COB, 4:30 p.m., and should be addressed to Michael Vidrine, Director, Sanitarian Services, P.O. Box 4489, Baton Rouge, LA 70821.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Monday, September 11, 2023**.** If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:00 a.m. on Monday, September 25, 2023 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after September 11, 2022. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Stephen R. Russo, JD
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Brian R. Warren
Dept.: Louisiana Department of Health
Phone: 225-342-7514
Office: Office of Public Health
Return Address: 628 N. 4th Street,
Baton Rouge, LA 70802

Rule Title: Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices

Date Rule Takes Effect: August 20, 2023

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule change is anticipated to increase Louisiana Department of Health (LDH), Office of Public Health expenditures by approximately $479 SGF in FY24 associated with publication costs.

In compliance with Act 498 of the 2022 RLS, the LDH proposes to amend Chapter 5 of Title 49, Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices by updating the regulatory framework for consumable hemp products. Specifically, the rule provides LDH with the authority to:

- Require proof that consumable hemp products for which registration is sought are not designed or intended for other than oral consumption or topical use.
- Deny requested registration of consumable hemp products that are designed or intended for other than oral consumption or topical use.
- Authorize LDH to revoke the registration of consumable hemp products that are designed or intended for other than oral consumption or topical use.

The rule also clarifies language and makes technical updates related to registering consumable hemp products

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL

GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units as a result of this proposed rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

Given that LDH will revoke or deny registration of consumable hemp products that are not designed or intended for oral consumption or topical use, manufacturers or retailers of these products may be negatively impacted as they will not be able to sell these products in Louisiana.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule has no known effect on competition and employment.

Signature of Agency Head or Designee	Legislative Fiscal Officer or Designee
Doris Brown Assistant Secretary, Office of Public Health Typed Name & Title of Agency Head or Designee	
Date of Signature	Date of Signature