

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

August 28, 2020

VIA HAND DELIVERY

Ms. Marjorie C. Holladay, Chief Attorney
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400

RECEIVED
2020 AUGUST 28
JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

**Re: Dept. of Health: Office of Medical Marijuana Use
Rule 64ER20-32, F.A.C. – Notice of Emergency Rule**

Dear Ms. Holladay:

1. Enclosed are the following document(s) regarding the above-referenced matter:
2. The referenced *Notice* which will publish in the FLORIDA ADMINISTRATIVE REGISTER on **August 26, 2020 (Vol. 46, No. 169)**
3. Materials incorporated by reference:
Food Allergen Labeling and Consumer Protection Act of 2004, Public Law 108-282, Title II (effective 8/2/2004)

Please date-stamp the document and return a stamped copy to me at the address below. The handling attorney is **Alysson Bradley** who can be reached at **617-1414**.

Sincerely,

Deann L. Peltz
Senior Legal Assistant

/dlp

Enclosures

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Notice of Emergency Rule

JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

DEPARTMENT OF HEALTH

RULE NO.: RULE TITLE:

64ER20-32 MMTC Packaging and Labeling

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC, HEALTH, SAFETY OR WELFARE: Pursuant to Chapter 2020-114, § 14, Laws of Florida, the Department is not required to make findings of an immediate danger to the public, health, safety, or welfare.

REASONS FOR CONCLUDING THAT THE PROCEDURE USED IS FAIR UNDER THE CIRCUMSTANCES: The Department of Health is directed by Chapter 2020-114, § 14, Laws of Florida, to adopt emergency rules to implement section 381.986, Florida Statutes.

SUMMARY OF THE RULE: Emergency Rule 64ER20-32 describes packaging and labeling requirements for medical marijuana and Low-THC cannabis products dispensed by medical marijuana treatment centers.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Christopher Ferguson at Christopher.Ferguson@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64ER20-32 MMTC Packaging and Labeling.

(1) All usable product shall be placed inside of a receptacle at the MMTC's department-approved processing facility. Receptacles shall be placed inside of a package with a patient package insert that complies with subsection (10) of this rule before the usable product is dispensed by an MMTC.

(2) Before dispensing usable product in any receptacle and packaging, an MMTC shall comply with the procedure in Rule 64-4.023, F.A.C., to obtain department approval of the use of the receptacle, label, and package.

(3) Receptacles for all usable products shall comply with the following:

(a) The receptacle shall be child resistant. In the case of multiple-use usable products and multi-serving edibles, the receptacle shall be resealable such that it continues to be child resistant after each use or serving.

(b) The receptacle shall have a firmly affixed and readable label(s) that includes only the information required or permitted by s. 381.986(8)(e)11.f., F.S., and this rule. An MMTC may affix multiple labels to the receptacle as needed to convey the required or permissible information. Labels may be accordion, expandable, extendable, or layered to permit labeling of small receptacles as long as none of the required information is obstructed.

(c) All required information on the label(s) shall be prominently and conspicuously placed thereon.

(d) The universal symbol on every receptacle shall be at least ¼ inch wide and ¼ inch high and shall be placed on the outer layer of receptacle labeling.

(e) The receptacle shall not include depictions of the product or any graphics or images other than one image of the MMTC's department-approved logo and the universal symbol.

(f) The receptacle may include instructions, health information, or warnings and precautions. An MMTC shall not include unsubstantiated claims that the usable product cures any medical condition.

(4) Receptacles for derivative products that are not edibles shall be a single solid color or clear and shall not be neon. Where applicable, the lid of a receptacle shall be the same single solid color or white.

(5) Receptacles and wrapping for edibles shall comply with the following:

(a) The receptacle shall be plain, opaque, and white.

(b) The receptacle shall have a firmly affixed and readable label(s) that includes the following:

1. A list of all the edible's ingredients in order of prominence which uses the common or usual name of food ingredients and identifies major allergens in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, Public Law 108-282, Title II (effective 8/2/2004), which is incorporated by reference and available at <https://knowthefactsmmj.com/rules-and-regulations/>;

2. Storage instructions;

3. An expiration date;

4. A legible and prominent warning to keep away from children and pets; and

5. A warning stating that the edible has not been produced or inspected pursuant to federal food safety laws.

(c) Each edible shall be individually sealed in plain, opaque, and white wrapping marked only with the marijuana universal symbol.

1. Any edible dispensed as a single serving portion shall be individually wrapped and placed inside of the receptacle.

2. Multi-serving lozenges, gelatins, and chocolates may be wrapped as single serving portions or together as a multi-serving edible and placed inside of the receptacle.

3. Each single serving portion of a multi-serving baked good shall be individually wrapped and placed inside of the receptacle.

4. Each single serving portion of a multi-serving drink powder shall be individually wrapped and placed inside of the receptacle.

(6) Receptacles for usable products in a form for smoking shall comply with the following:

(a) The receptacle shall be plain, opaque, and white.

(b) The receptacle shall have a firmly affixed and readable label that includes the following:

1. A legible and prominent warning to keep the product away from children; and

2. A warning stating that marijuana smoke contains carcinogens and may negatively affect health.

(7) Packaging for derivative products that are not edibles shall comply with the following:

(a) A package shall be one single solid color and may have one additional accent color, not including the department-approved logo, universal symbol, and text. The single solid color and the additional accent color shall not be neon.

(b) The text on a package shall be a single solid color which shall not be neon.

(c) The universal symbol shall be printed on the package and shall be no less than 10 percent of the overall surface area of the package.

(d) The package shall identify every ingredient, in order of prominence, unless the ingredients are identified on the receptacle label or patient package insert.

(8) Packaging for edibles and marijuana in a form for smoking shall comply with the following:

(a) The package shall be plain, opaque, and white.

(b) The universal symbol shall be printed on the package and shall be no less than 10 percent of the overall surface area of the package.

(9) Packaging for all usable products may include the following permissive information:

(a) The MMTC's department-approved logo;

(b) Any information required by ss. 381.986(8)(e)11.f. and 12., F.S.;

(c) A Quick Response (QR) code, or similar bar code or smart code that allows a patient to access the usable product's certificate of analysis and information related to the usable product being dispensed, provided that the information conveyed is information that is permitted to appear on the receptacle label, package, or patient package insert. Upon request of a patient or caregiver, an MMTC shall provide paper copies of the information available pursuant to this paragraph.

(d) Product Stock-Keeping Unit (SKU), barcode, or other similar product identifier;

(e) Cultivar name in black or white, print lettering, in a sans-serif font which shall not be larger than 12-point font. If the cultivar name does not comply with s. 381.986(8)(e)11.f.(VI), F.S., it shall be abbreviated on the package; and

(f) Instructions, health information, or warnings and precautions. An MMTC shall not include unsubstantiated claims that the usable product cures any medical condition.

(10) The package for every usable product shall include a patient package insert intended for the patient or caregiver that provides the information required by s. 381.986(8)(e)12., F.S., and no additional information, except that the patient package insert may include the information identified in subsection (9).

(11) Notwithstanding the foregoing, this rule shall not preclude an MMTC from including information on a receptacle label, or package that is otherwise required by law or rule.

(12) An MMTC shall have 6 months from the effective date of this rule to comply with requirements contained herein. Variance requests seeking approval of new edibles shall immediately comply with the requirements of this rule.

Rulemaking Authority 381.986(8)(k), 381.986(10)(h), 381.0011(1), 381.0011(2), 381.0011(7), FS. Law Implemented 381.986(8)(e) FS. History-New.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE 8-26-2020

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(T) Section 108(b)(3) of Public Law 90-399 is amended by striking “section 201(w) as added by this Act” and inserting “section 201(v)”.

21 USC 360b
note.

(6) REGULATIONS.—On the date of enactment of this Act, the Secretary of Health and Human Services shall implement sections 571 and 573 of the Federal Food, Drug, and Cosmetic Act and subsequently publish implementing regulations. Not later than 12 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 573 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 573 of the Federal Food, Drug, and Cosmetic Act. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 572 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 36 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 572 of the Federal Food, Drug, and Cosmetic Act. Not later than 30 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 571 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 42 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 571 of the Federal Food, Drug, and Cosmetic Act. These timeframes shall be extended by 12 months for each fiscal year, in which the funds authorized to be appropriated under subsection (i) are not in fact appropriated.

Effective date.
Deadlines.
Publication.
21 USC 360ccc
note.

(7) OFFICE.—The Secretary of Health and Human Services shall establish within the Center for Veterinary Medicine (of the Food and Drug Administration), an Office of Minor Use and Minor Species Animal Drug Development that reports directly to the Director of the Center for Veterinary Medicine. This office shall be responsible for overseeing the development and legal marketing of new animal drugs for minor uses and minor species. There is authorized to be appropriated to carry out this subsection \$1,200,000 for fiscal year 2004 and such sums as may be necessary for each fiscal year thereafter.

Government
organization.
21 USC 393 note.

(8) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out section 573(b) of the Federal Food, Drug, and Cosmetic Act (as added by this section) \$1,000,000 for the fiscal year following publication of final implementing regulations, \$2,000,000 for the subsequent fiscal year, and such sums as may be necessary for each fiscal year thereafter.

Appropriation
authorization.

TITLE II—FOOD ALLERGEN LABELING AND CONSUMER PROTECTION

Food Allergen
Labeling and
Consumer
Protection Act of
2004.
21 USC 301 note.

SEC. 201. SHORT TITLE.

This title may be cited as the “Food Allergen Labeling and Consumer Protection Act of 2004”.

SEC. 202. FINDINGS.

Congress finds that—

21 USC 343 note.

(1) it is estimated that—

(A) approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies; and

(B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;

(2)(A) eight major foods or food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—account for 90 percent of food allergies;

(B) at present, there is no cure for food allergies; and

(C) a food allergic consumer must avoid the food to which the consumer is allergic;

(3)(A) in a review of the foods of randomly selected manufacturers of baked goods, ice cream, and candy in Minnesota and Wisconsin in 1999, the Food and Drug Administration found that 25 percent of sampled foods failed to list peanuts or eggs as ingredients on the food labels; and

(B) nationally, the number of recalls because of unlabeled allergens rose to 121 in 2000 from about 35 a decade earlier;

(4) a recent study shows that many parents of children with a food allergy were unable to correctly identify in each of several food labels the ingredients derived from major food allergens;

(5)(A) ingredients in foods must be listed by their “common or usual name”;

(B) in some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen; and

(C) in other cases, the ingredients may be declared as a class, including spices, flavorings, and certain colorings, or are exempt from the ingredient labeling requirements, such as incidental additives; and

(6)(A) celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs;

(B) the current recommended treatment is avoidance of glutes in foods that are associated with celiac disease; and

(C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population.

SEC. 203. FOOD LABELING; REQUIREMENT OF INFORMATION REGARDING ALLERGENIC SUBSTANCES.

(a) **IN GENERAL.**—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

“(w)(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

“(A) the word ‘Contains’, followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

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“(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when—

“(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

“(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

“(2) As used in this subsection, the term ‘name of the food source from which the major food allergen is derived’ means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term ‘name of the food source from which the major food allergen is derived’ means the name of the specific type of nut or species of fish or Crustacean shellfish.

“(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

Federal Register,
publication.

“(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

“(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

“(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

“(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

“(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

“(D) A determination regarding a petition under this paragraph shall constitute final agency action.

“(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary’s response to each.

Public
information.
Deadline.

“(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing—

“(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

“(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

Deadlines.

“(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

Public information. Deadline.

“(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

“(x) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.”

21 USC 343 note.

(b) EFFECT ON OTHER AUTHORITY.—The amendments made by this section that require a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to require a label or labeling for other food allergens.

(c) CONFORMING AMENDMENTS.—

(1) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) (as amended by section 102(b)) is amended by adding at the end the following:

“(qq) The term ‘major food allergen’ means any of the following:

“(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

“(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

“(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

“(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).”

(2) Section 403A(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(2)) is amended by striking “or 403(i)(2)” and inserting “403(i)(2), 403(w), or 403(x)”.

Applicability. 21 USC 321 note.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to any food that is labeled on or after January 1, 2006.

SEC. 204. REPORT ON FOOD ALLERGENS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(1)(A) analyzes—

(i) the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens, including contamination caused by the use by manufacturers of the same production line to produce both products for which major food allergens are intentional ingredients and products for which major food allergens are not intentional ingredients; and

(ii) the ways in which foods produced on dedicated production lines are unintentionally contaminated with major food allergens; and

(B) estimates how common the practices described in subparagraph (A) are in the food industry, with breakdowns by food type as appropriate;

(2) advises whether good manufacturing practices or other methods can be used to reduce or eliminate cross-contact of foods with the major food allergens;

(3) describes—

(A) the various types of advisory labeling (such as labeling that uses the words “may contain”) used by food producers;

(B) the conditions of manufacture of food that are associated with the various types of advisory labeling; and

(C) the extent to which advisory labels are being used on food products;

(4) describes how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms;

(5) states the number of inspections of food manufacturing and processing facilities conducted in the previous 2 years and describes—

(A) the number of facilities and food labels that were found to be in compliance or out of compliance with respect to cross-contact of foods with residues of major food allergens and the proper labeling of major food allergens;

(B) the nature of the violations found; and

(C) the number of voluntary recalls, and their classifications, of foods containing undeclared major food allergens; and

(6) assesses the extent to which the Secretary and the food industry have effectively addressed cross-contact issues.

SEC. 205. INSPECTIONS RELATING TO FOOD ALLERGENS.

21 USC 374a.

The Secretary of Health and Human Services shall conduct inspections consistent with the authority under section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) of facilities in which foods are manufactured, processed, packed, or held—

(1) to ensure that the entities operating the facilities comply with practices to reduce or eliminate cross-contact of a food

with residues of major food allergens that are not intentional ingredients of the food; and

(2) to ensure that major food allergens are properly labeled on foods.

Deadlines.
Regulations.
21 USC 343 note.

SEC. 206. GLUTEN LABELING.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term “gluten-free” on the labeling of foods. Not later than 4 years after the date of enactment of this Act, the Secretary shall issue a final rule to define, and permit use of, the term “gluten-free” on the labeling of foods.

42 USC 242r.

SEC. 207. IMPROVEMENT AND PUBLICATION OF DATA ON FOOD-RELATED ALLERGIC RESPONSES.

(a) **IN GENERAL.**—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) the collection of, and publish as it becomes available, national data on—

- (1) the prevalence of food allergies;
- (2) the incidence of clinically significant or serious adverse events related to food allergies; and
- (3) the use of different modes of treatment for and prevention of allergic responses to foods.

(b) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

42 USC 243 note.

SEC. 208. FOOD ALLERGIES RESEARCH.

Government
organization.

(a) **IN GENERAL.**—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene an ad hoc panel of nationally recognized experts in allergy and immunology to review current basic and clinical research efforts related to food allergies.

Deadline.
Public
information.

(b) **RECOMMENDATIONS.**—Not later than 1 year after the date of enactment of this Act, the panel shall make recommendations to the Secretary for enhancing and coordinating research activities concerning food allergies, which the Secretary shall make public.

SEC. 209. FOOD ALLERGENS IN THE FOOD CODE.

The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.

SEC. 210. RECOMMENDATIONS REGARDING RESPONDING TO FOOD-RELATED ALLERGIC RESPONSES.

42 USC 300d–2
note.

The Secretary of Health and Human Services shall, in providing technical assistance relating to trauma care and emergency medical services to State and local agencies under section 1202(b)(3) of the Public Health Service Act (42 U.S.C. 300d–2(b)(3)), include technical assistance relating to the use of different modes of treatment for and prevention of allergic responses to foods.

Approved August 2, 2004.

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LEGISLATIVE HISTORY—S. 741:

HOUSE REPORTS: No. 108–608 (Comm. on Energy and Commerce).

SENATE REPORTS: No. 108–226 (Comm. on Health, Education, Labor, and Pensions).

CONGRESSIONAL RECORD, Vol. 150 (2004):

Mar. 8, considered and passed Senate.

July 20, considered and passed House.

