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Title 21 Code of Federal Regulations

PART 1308 — SCHEDULES OF CONTROLLED SUBSTANCES

EXEMPT CANNABIS PLANT MATERIAL, AND PRODUCTS MADE THEREFROM, THAT CONTAIN TETRAHYDROCANNABINOLS

§1308.35 Exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols.

(a) Any processed plant material or animal feed mixture containing any amount of tetrahydrocannabinols (THC) that is both:

(1) Made from any portion of a plant of the genus *Cannabis* excluded from the definition of marijuana under the Act [i.e., the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination] and (2) Not used, or intended for use, for human consumption, has been exempted by the Administrator from the application of the Act and this chapter.

(b) As used in this section, the following terms shall have the meanings specified:

(1) The term processed plant material means cannabis plant material that has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption.

(2) The term animal feed mixture means sterilized cannabis seeds mixed with other ingredients (not derived from the cannabis plant) in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption).

(3) The term used for human consumption means either:

(i) Ingested orally or (ii) Applied by any means such that THC enters the human body.

(4) The term intended for use for human consumption means any of the following:

(i) Designed by the manufacturer for human consumption; (ii) Marketed for human consumption; or (iii) Distributed, exported, or imported, with the intent that it be used for human consumption.

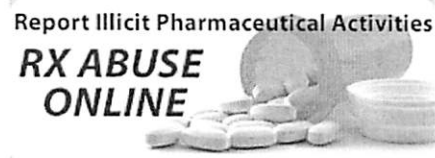
(c) In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (**21 U.S.C. 885(a)(1)**). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to **Sec. 1308.23**, the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.

[66 FR 51544, Oct. 9, 2001]

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Title 21 United States Code (USC) Controlled Substances Act

SUBCHAPTER I — CONTROL AND ENFORCEMENT

Part E — Administrative and Enforcement Provisions

§885. Burden of proof; liabilities

(a) Exemptions and exceptions; presumption in simple possession offenses

(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

(2) In the case of a person charged under section 844(a) of this title with the possession of a controlled substance, any label identifying such substance for purposes of section 353(b)(2) of this title shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

(b) Registration and order forms

In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this subchapter, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) Use of vehicles, vessels, and aircraft

The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this subchapter shall be on the persons engaged in such use.

(d) Immunity of Federal, State, local and other officials

Except as provided in sections 2234 and 2235 of title 18, no civil or criminal liability shall be imposed by virtue of this subchapter upon any duly authorized Federal officer lawfully engaged in the enforcement of this subchapter, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

(Pub. L. 91-513, title II, §515, Oct. 27, 1970, 84 Stat. 1279.)

References in Text

Schedule I, referred to in subsec. (c), is set out in section 812(c) of this title.

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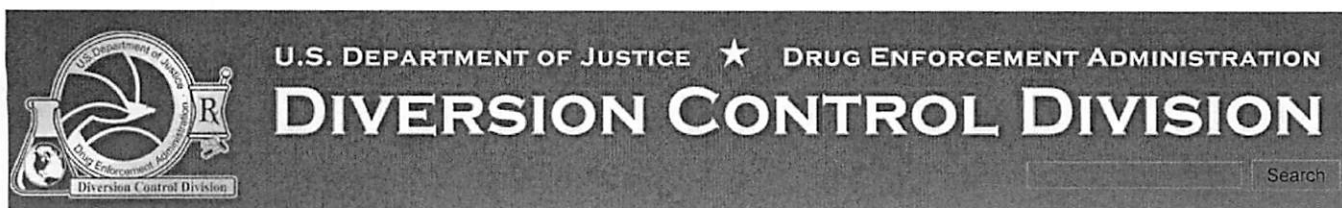
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Title 21 Code of Federal Regulations

PART 1308 — SCHEDULES OF CONTROLLED SUBSTANCES

EXEMPT CHEMICAL PREPARATIONS

§1308.23 Exemption of certain chemical preparations; application.

(a) The Administrator may, by regulation, exempt from the application of all or any part of the Act any chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal, if the preparation or mixture either:

- (1) Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse (the type of packaging and the history of abuse of the same or similar preparations may be considered in determining the potential for abuse of the preparation or mixture); or
- (2) Contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a narcotic controlled substance, the preparation or mixture must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

(b) Any person seeking to have any preparation or mixture containing a controlled substance and one or more noncontrolled substances exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(c) An application for an exemption under this section shall contain the following information:

- (1) The name, address, and registration number, if any, of the applicant;
- (2) The name, address, and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;
- (3) The exact trade name or other designation of the preparation or mixture;
- (4) The complete qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled and noncontrolled substances);
- (5) The form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);
- (6) The dimensions or capacity of the immediate container of the preparation or mixture;
- (7) The label and labeling, as defined in **part 1300** of this chapter, of the immediate container and the commercial containers, if any, of the preparation or mixture;
- (8) A brief statement of the facts which the applicant believes justify the granting of an exemption under this paragraph, including information on the use to which the preparation or mixture will be put;
- (9) The date of the application; and
- (10) Which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under subsection 402(a)(8) of the Act (**21 U.S.C. 842(a)(8)**) or any other law restricting public disclosure of information.

(d) The Administrator may require the applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) or requested pursuant to paragraph (d) is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the Federal Register his order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

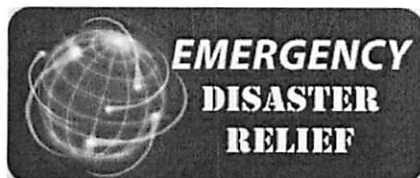
(f) The Administrator may at any time revoke or modify any exemption granted pursuant to this section by following the procedures set forth in paragraph (e) of this section for handling an application for an exemption which has been accepted for filing. The Administrator may also modify or revoke the criteria by which exemptions are granted (and thereby modify or revoke all preparations and mixtures granted under the old criteria) and modify the scope of exemptions at any time.

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[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 62 FR 13968, Mar. 24, 1997; 75 FR 10678, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

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