

§ 1308.41

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 pur-

21 CFR Ch. II (4–1–08 Edition)

suant to §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]

HEARINGS

§ 1308.41 Hearings generally.

In any case where the Administrator shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§1308.42–1308.51, and by §§1316.41–1316.67 of this chapter.

§ 1308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to §1308.43, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order are set forth in part 1316 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1308.43 Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Administrator in the following form:

Drug Enforcement Administration, Justice

§ 1308.43

(Date)
ADMINISTRATOR, DRUG ENFORCEMENT
ADMINISTRATION
*Department of Justice,
Washington, DC 20537.*

DEAR SIR: The _____ undersigned
_____ hereby peti-
tions the Administrator to initiate pro-
ceedings for the issuance (amendment or re-
peal) of a rule or regulation pursuant to sec-
tion 201 of the Controlled Substances Act.

Attached hereto and constituting a part of
this petition are the following:

(A) The proposed rule in the form proposed
by the petitioner. (If the petitioner seeks the
amendment or repeal of an existing rule, the
existing rule, together with a reference to
the section in the Code of Federal Regula-
tions where it appears, should be included.)

(B) A statement of the grounds which the
petitioner relies for the issuance (amend-
ment or repeal) of the rule. (Such grounds
shall include a reasonably concise statement
of the facts relied upon by the petitioner, in-
cluding a summary of any relevant medical
or scientific evidence known to the peti-
tioner.)

All notices to be sent regarding this peti-
tion should be addressed to:

(Name)

(Street Address)

(City and State)

Respectfully yours,

(Signature of petitioner)

(c) Within a reasonable period of
time after the receipt of a petition, the
Administrator shall notify the peti-
tioner of his acceptance or nonaccept-
ance of the petition, and if not accept-
ed, the reason therefor. The Adminis-
trator need not accept a petition for
filing if any of the requirements pre-
scribed in paragraph (b) of this section
is lacking or is not set forth so as to be
readily understood. If the petitioner
desires, he may amend the petition to
meet the requirements of paragraph (b)
of this section. If accepted for filing, a
petition may be denied by the Adminis-
trator within a reasonable period of
time thereafter if he finds the grounds
upon which the petitioner relies are

not sufficient to justify the initiation
of proceedings.

(d) The Administrator shall, before
initiating proceedings for the issuance,
amendment, or repeal of any rule ei-
ther to control a drug or other sub-
stance, or to transfer a drug or other
substance from one schedule to an-
other, or to remove a drug or other
substance entirely from the schedules,
and after gathering the necessary data,
request from the Secretary a scientific
and medical evaluation and the Sec-
retary's recommendations as to wheth-
er such drug or other substance should
be so controlled, transferred, or re-
moved as a controlled substance. The
recommendations of the Secretary to
the Administrator shall be binding on
the Administrator as to such scientific
and medical matters, and if the Sec-
retary recommends that a drug or
other substance not be controlled, the
Administrator shall not control that
drug or other substance.

(e) If the Administrator determines
that the scientific and medical evalua-
tion and recommendations of the Sec-
retary and all other relevant data con-
stitute substantial evidence of poten-
tial for abuse such as to warrant con-
trol or additional control over the drug
or other substance, or substantial evi-
dence that the drug or other sub-
stances should be subjected to lesser
control or removed entirely from the
schedules, he shall initiate proceedings
for control, transfer, or removal as the
case may be.

(f) If and when the Administrator de-
termines to initiate proceedings, he
shall publish in the FEDERAL REGISTER
general notice of any proposed rule
making to issue, amend, or repeal any
rule pursuant to section 201 of the Act.
Such published notice shall include a
statement of the time, place, and na-
ture of any hearings on the proposal in
the event a hearing is requested pursu-
ant to §1308.44. Such hearings may not
be commenced until after the expira-
tion of at least 30 days from the date
the general notice is published in the
FEDERAL REGISTER. Such published no-
tice shall also include a reference to
the legal authority under which the
rule is proposed, a statement of the
proposed rule, and, in the discretion of

§ 1308.44

the Administrator, a summary of the subjects and issues involved.

(g) The Administrator may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated and amended at 62 FR 13968, Mar. 24, 1997]

§ 1308.44 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the FEDERAL REGISTER, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to § 1308.41 shall, within 30 days after the date of publication of the notice of hearing in the FEDERAL REGISTER, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in § 1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any interested person fails to file a request for a hearing; or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

21 CFR Ch. II (4-1-08 Edition)

(e) If all interested persons waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1308.45 without a hearing.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated and amended at 62 FR 13968, Mar. 24, 1997]

§ 1308.45 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13968, Mar. 24, 1997]

§ 1308.46 Control required under international treaty.

Pursuant to section 201(d) of the Act (21 U.S.C. 811(d)), where control of a substance is required by U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971, the Administrator shall issue and publish in the FEDERAL REGISTER an order controlling such substance under the schedule he deems most appropriate to carry out obligations. Issuance of such an order shall be without regard to the findings required by subsections 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 1308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811 (a) and (b)). An order controlling a substance shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Administrator finds that conditions of public health or safety