AUTHORITY: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

SOURCE: 38 FR 8254, Mar. 30, 1973, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1308.01 Scope of part 1308.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812), as they are changed, updated, and republished from time to time, are set forth in this part.

§ 1308.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 of contr. 21 Trs paro 1302 of this chpte. E

(26) Psilocyn 7438
(27) Tetrahydrocannabinols 7370
Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
Δ1 cis or trans tetrahydrocannabinol, and their optical isomers
Δ6 cis or trans tetrahydrocannabinol, and their optical isomers
Δ3,4 cis or trans tetrahydrocannabinol, and its optical isomers
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)
(28) Ethylamine analog of phencyclidine 7455
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE
(29) Pyrrolidine analog of phencyclidine 7458
Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(30) Thiophene analog of phencyclidine 7470
Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP
(31) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine 7473
Some other names: TCPy

(e) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate) 2010

(f) *Anabolic steroids.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids 4000

(g) *Hallucinogenic substances.*

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a softgelatin capsule in a U.S. Food and Drug Administration approved product.7369.

[Some other names for dronabinol: (6a*R*,10a*R*)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo[*b*,*d*]pyran-1-ol] or (-)-delta-9-(*trans*)-tetrahydrocannabinol]

(2) [Reserved]

[39 FR 22142, June 20, 1974, as amended at 41
230g]trahydr5 .0[illegible]

b[illegible] *r*[illegible]

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.

[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]

§ 1308.24 Exempt chemical preparations.

(a) The chemical preparations and mixtures approved pursuant to § 1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and § 1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section. Substances set forth in paragraph (j) of this section shall be exempt from the application of sections 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 825–829, 952–954) and §§ 1301.71—1301.73 and 1301.74 (a), (b), (d), (e) and (f) of this chapter to the extent as hereinafter may be provided.

(b) Registration and security Any person who manufactures an exempt chemical preparation or mixture must be registered under the Act and comply with all relevant security requirements regarding controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to be registered under the Act to handle that preparation, and the preparation is not required to be stored in accordance with security requirements regarding controlled substances.

(c) Labeling: In lieu of the requirements set forth in part 1302 of this chapter, the label and the labeling of an exempt chemical preparation must be prominently marked with its full trade name or other description and the name of the manufacturer or sp-

of Justice, Washington, DC 20537. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to maintain records or file reports.

(e) Quotas, order forms, prescriptions, import, export and transshipment requirements: Once an exempt chemical preparation is in the form described in paragraph (i) of this section, the requirements regarding quotas, order forms, prescriptions, import permits and declarations, export permit and declarations, and transshipment and intransit permits and declarations do not apply. These requirements do apply, however, to any controlled substances used in manufacturing the exempt chemical preparation before it is in the form described in paragraph (i) of this section.

(f) Criminal penalties: No exemption granted pursuant to §1308.23 affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the exempt chemical preparation. Distribution, possession, and use of an exempt chemical preparation are lawful for registrants and nonregistrants only as long as such distribution, possession, or use is intended for laboratory, industrial, or educational purposes and not for immediate or subsequent administration to a human being or other animal.

(g) Bulk materials: For materials exempted in bulk quantities, the Administrator may prescribe requirements other than those set forth in paragraphs (b) through (e) of this section on a case-by-case basis.

(h) Changes in chemical preparations: Any change in the quantitative or qualitative composition of the preparation or mixture after the date of application, or change in the trade name or other designation of the preparation or mixture, set forth in paragraph (i) of this section, requires a new application for exemption.

(i) A listing of exempt chemical preparations may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

(j) The following substances are designated as exempt chemical preparations for the purposes set forth in this section.

(1) *[Reserved]* When packaged in a sealed, oxygen-free environment, under nitrogen pressure, safeguarded against exposure to the air.

(2) *[Reserved]*

(3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for

(4) Details of synergisms and antag-

(5) Deterrent effects of the noncon-

(6) Complete copies of all literature

(7) Reported instances of abuse.
(8) Reported and anticipated adverse effects.
(9) Number of dosage units produced

(c) Within a reasonable period of time after the receipt of an application

ceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an applica-

ments prescribed in paragraph (b) of

ments of paragraph (b) of this section. If accepted for filing, the Administrator shall publish in the FEDERAL

EXEMPT ANABOLIC STEROID PRODUCTS

§ 1308.33 Exemption of certain anabolic steroid products; application.

(a) The Administrator, upon the recommendation of the Secretary of Health and Human Services, may by regulation, exempt from the application of all or any part of the Act any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter if, because of its concentration, preparation, mixture or delivery system, it has no significant potential for abuse (Pub. L. 101-647 section 1903(a)).

(b) Any person seeking to have any compound, mixture, 295 preparation

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