**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

## Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule I to Schedule II; Statement of Policy

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Final Rule and Statement of Policy.

**SUMMARY:** This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to transfer U.S. Food and Drug Administration (FDA) approved drug products that consist of synthetic dronabinol in sesame oil encapsulated in soft gelatin capsules from Schedule I into Schedule II of the Controlled Substances Act (CSA). Dronabinol is the synthetic equivalent of the isomer of delta-9-tetrahydrocannabinol (THC) which is the principal psychoactive substance in *Cannabis sativa L.*, marijuana. This action is based on a finding that U.S. Food and Drug Administration approved drug products which contain dronabinol fit the statutory criteria for inclusion in Schedule II of the CSA. As a result of this rule, the regulatory controls and criminal sanctions of Schedule II of the CSA will apply to the manufacture, distribution, importation and exportation of dronabinol pharmaceutical products. This rule does not affect the Schedule I status of any other substance, mixture or preparation which is currently included in 21 CFR 1308.11(d)(21), Tetrahydrocannabinols. The Administrator herein also issues a statement of policy regarding review, under the public interest criteria of 21 U.S.C. 823(f) and 824(a)(4), of the DEA registrations of practitioners who distribute or dispense dronabinol for purposes at variance with the FDA approved indications for use of the approved product. A notice is published elsewhere in this isue of the **Federal Register** that withdraws the proposed rule entitled Changes in Protocol Requirements for Researchers and Prescription Requirements for Practitioners (50 FR 42184–42186, October 18, 1985).

**EFFECTIVE DATE:** May 13, 1986.

**FOR FURTHER INFORMATION CONTACT:** Howard McClain, Jr., Chief, Drug Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone: (202) 633–1366.

**SUPPLEMENTARY INFORMATION:**

### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

A proposed rule was published in the **Federal Register** on October 18, 1985 (50 FR 42186–42187), proposing that dronabinol in sesame oil and encapsulated in soft gelatin capsules in a drug product approved by the U.S. Food and Drug Administration be transferred from Schedule I to Schedule II of the Controlled Substances Act (21 U.S.C. 801 et seq.). Concurrently, a proposal was published which proposed changes in protocol requirements for researchers and prescription requirements for practitioners (50 FR 42184–42186). Interested persons were given until November 18, 1985, to submit comments or objections regarding each of the proposals.

Thirteen individuals or organizations availed themselves of the opportunity to comment, object or request an administrative hearing. Two organizations, Cannabis Corporation of America and National Organization for the Reform of Marijuana Laws (NORML), requested hearings. Both requests for hearings were subsequently withdrawn. Comments or objections were submitted by or on behalf of the following: Alliance for Cannabis Therapeutics, American College of Neuropsychopharmacology, American Medical Association, American Pharmaceutical Association, Arkansas Department of Health, Committee on Problems of Drug Dependence, Inc., Mr. Ansis M. Helmanis, the law offices of Kleinfeld, Kaplan and Becker, Marcos A. S. Lima, M.D., H. G. Pars Pharmaceutical Laboratories and the Pharmaceutical Manufacturers Association.

Having considered the comments and objections presented by the above listed parties, the requirements of the Controlled Substances Act and the Convention on Psychotropic Substances (T.I.A.S. 9725, July 15, 1980), the Administrator has decided (a) to proceed with the rescheduling of dronabinol as proposed at 50 FR 42186–42187 and (b) to issue a statement of policy regarding review of the distribution or dispensing of dronabinol by practitioner registrants which deviates from approved medical use to insure compliance with the obligations of the United States as a signatory to the Convention on Psychotropic Substances. The previously proposed regulations relating to dronabinol are withdrawn elsewhere in this issue of the **Federal Register.**

*(a) Transfer of FDA Approved Dronabinol Drug Products From Schedule I to Schedule II*

Having considered the comments and objections presented by the above listed parties and based on the investigations and review of the Drug Enforcement Administration, with attention to the obligations of the United States under the Convention on Psychotropic Substances, and relying on the scientific and medical evaluation and recommendation of the Assistant Secretary for Health of the Department of Health and Human Services, acting on behalf of the Secretary of the Department of Health and Human Services, in accordance with 21 U.S.C. 811(b), and the Food and Drug Administration approval of a new drug application for Marinol capsules, the Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

1. Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product has a high potential for abuse;

2. Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and

3. Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product may lead to severe psychological or physical dependence.

The above findings are consistent with placement of dronabinol approved drug products into Schedule II of the CSA. The transfer of the product from Schedule I to Schedule II is effective on May 13, 1986 with selected implementation dates as indicated. In the event that this imposes special hardships on any registrant, the Drug Enforcement Administration will entertain any justified request for an extention of time to comply with the Schedule II regulations. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports a FDA approved dronabinol drug product, or who engages in research or conducts instructional activities with such a substance must be registered to conduct such activities in accordance with Parts

1301 and 1311 of Title 21 of the Code of Federal Regulations. Any person currently registered to handle dronabinol in Schedule I may continue activities under that registration until approved or denied registration in Schedule II, provided such registrant has filed an application for registration in Schedule II with DEA on or before June 12, 1986. Any persons not currently registered and proposing to engage in such activities may not conduct activities with the drug product until properly registered in Schedule II.

2. *Security.* FDA approved dronabinol drug products must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), (c) and (d), 1301.73, 1301.74, 1301.75(b) and (c) and § 1301.76 of Title 21 of the Code of Federal Regulations. Dronabinol and all mixtures, compounds and preparations thereof, except for dronabinol in sesame oil and encapsulated in soft gelatin capsules in a FDA approved drug product, remain in Schedule I and must be stored in accordance with § 1301.75(a).

3. *Labeling and Packaging.* All labels and labeling for commercial containers of FDA approved dronabinol drug products must comply with the requirements of §§ 1302.03–1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations. Current products distributed or dispensed for approved research and labeled as Schedule I products may continue to be distributed and dispensed until May 13, 1987.

4. *Quotas.* All persons required to obtain quotas for dronabinol drug products shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of FDA approved dronabinol drug product shall take an inventory, pursuant to § 1304.04 and §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks on hand as of June 12, 1986.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21–1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding FDA approved dronabinol drug products.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34–1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding FDA approved dronabinol drug products.

8. *Order Forms.* All registrants involved in the distribution of dronabinol drug products shall comply with the order form requirements of Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* FDA approved dronabinol drug products have been approved for use in medical treatment and the drug may be dispensed by prescription. All prescriptions for FDA approved dronabinol drug products shall comply with §§ 1306.01–1306.06 and §§ 1306.11–1306.15 of Title 21 of the Code of Federal Regulations.

10. *Importation and Exportation.* All importation and exportation of dronabinol drug products shall be in compliance with Parts 1311 and 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal Liability.* Any activity with respect to FDA approved dronabinol drug products not authorized by or in violation of the Controlled Substances Act or the Controlled Substances Import and Export Act continues to be unlawful. The applicable penalties after May 13, 1986 shall be those of a Schedule II substance.

12. *Other.* In all other respects, this order is effective on May 13, 1986.

*(b) Statement of Policy*

The Administrator takes special note of the fact that synthetic tetrahydrocannabinol in all forms, including dronabinol, remains internationally controlled in Schedule I of the Convention on Psychotropic Substances. Under the special obligations of the Convention, to which the United States is a party, relative to Schedule I substances, Article 7 requires in part that parties shall "prohibit all use except for scientific and *very limited medical purposes* . . ." (emphasis added). The Administrator also notes that the official "Commentary on the Convention on Psychotropic Substances" provides guidance to parties in meeting this obligation consistent with national laws and policies.

The Administrator finds that the existing requirements of Schedule II of the Controlled Substances Act can provide adequate controls and restrictions to comply with the obligations of the Convention on Psychotropic Substances when coupled with effective oversight and enforcement, such as provided for in the Dangerous Drug Diversion Control Act of 1984 (part B of chapter V of Title II of Pub. L. 98–473). The Administrator notes that experience has demonstrated that there are medical practitioners registered to dispense Schedule II substance who abuse that registration and prescribe or dispense Schedule II substances outside the scope of the legitimate medical practice.

On May 31, 1985, the Food and Drug Administration (FDA) approved the drug product, Marinol capsules, containing dronabinol for nausea associated with cancer treatment. Considering the nature of this drug, it is reasonable to assume that drug abusers will attempt to seek out practitioner registrants willing to prescribe the drug for abuse purposes, under the guise of legitimate medical practice, as frequently occurs with other Schedule II substances. DEA has encountered practitioners who attempt to justify illegal or improper distribution or dispensing by claiming unique knowledge of a drug's effectiveness for a broad range of medical indications. While it is expected that legitimate structured research programs may document additional medical indications for dronabinol, prescribing which deviates from the recognized approved medical use must be questioned in keeping with the United States obligations to prohibit all use except for scientific and very limited medical purposes.

Therefore, in keeping with sound domestic drug control policy and the United States obligations under the Convention on Psychotropic Substances, the Administrator hereby issues this statement of policy:

*Any person registered by DEA to distribute, prescribe, administer or dispense controlled substances in Schedule II who engages in the distribution or dispensing of dronabinol for medical indications outside the approved use associated with cancer treatment, except within the confines of a structured and recognized research program, may subject his or her controlled substances registration to review under the provisions of 21 U.S.C. 823(f) and 824(a)(4) as being inconsistent with the public interest. DEA will take action to revoke that registration if it is found that such distribution or dispensing constitutes a threat to the public health and safety, and in addition will pursue any criminal sanctions which may be warranted under 21 U.S.C. 841(a)(1).* See *United States* v. *Moore*, 423 U.S. 122 (1975).

The proposed rule which was published at 50 FR 42184–42186, October 18, 1985, entitled Changes in Protocol Requirements for Researchers and Prescription Requirements for Practitioners, is withdrawn elsewhere in this issue of the **Federal Register.**

Pursuant to sections 3(c)(3) and 3(e)(2)(C) of Executive Order 12291 (46

FR 13193), this statement of policy has been submitted for review by the Office of Management and Budget. In accordance with the provisions of 21 U.S.C. 811(a), this order to reschedule certain drug products which contain synthetic dronabinol from Schedule I to Schedule II is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements of Executive Order 12291.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the rescheduling of formulations which contain dronabinol, as ordered herein, will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354, September 19, 1980). This action will allow the marketing of a drug product which has been approved by the FDA.

Pursuant to the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], as redelegated to the Administrator of the Drug Enforcement Administration by 28 CFR 0.100, and for the reasons set forth above, the Administrator hereby orders that 21 CFR 1308.12 be amended as follows:

## PART 1308—[AMENDED]

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. 21 CFR 1308.12 is amended by redesignating the existing paragraph (f) as paragraph (g) and by adding a new paragraph (f), reading as follows:

**§ 1308.12 Schedule II.**

* * * * *

(f) *Hallucinogenic substances.*

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

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

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Dated: May 1, 1986.

**John C. Lawn,**

*Administrator, Drug Enforcement Administration.*

[FR Doc. 86-10724 Filed 5-12-86; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

### 30 CFR Part 914

### Approval of Permanent Program Amendments From the State of Indiana Under the Surface Mining Control and Reclamation Act of 1977

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

**ACTION:** Final rule.

**SUMMARY:** OSMRE is announcing the appproval of amendments to the Indiana Permanent Regulatory Program (hereinafter referred to as the Indiana program) received by OSMRE pursuant to the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

On January 31, 1986, Indiana submitted amendments to its program requirements regarding civil penalties, incidental boundary revisions and use of explosives.

After providing opportunity for public comment and conducting a thorough review of the program amendments, the Director, OSMRE, has determined that the amendments meet the requirements of SMCRA and the Federal regulations. Accordingly, the Director is approving these amendments. The Federal rules at 30 Part 914 which codify decisions concerning the Indiana program are being amended to implement this action.

This final rule is being made effective immediately in order to expedite the State program amendment process and encourage States to conform their programs to the Federal standards without undue delay; consistency of the State and Federal standards is required by SMCRA.

**EFFECTIVE DATE:** May 13, 1986

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard D. Rieke, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building and U.S. Courthouse, Room 522, 46 East Ohio Street, Indianapolis, Indiana 46204. Telephone: (317) 269-2600.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Information regarding the general background on the Indiana State program, including the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 **Federal Register** (47 FR 32071-32108). Subsequent actions concerning the Indiana program are identified in 30 CFR 914.15 and 30 CFR 914.16.

### II. Discussion of Proposed Amendment

On January 31, 1986, the Indiana Department of Natural Resources submitted to OSMRE pursuant to 30 CFR 732.17, proposed State program amendments for approval (Administrative Record No. IND 0453). The amendments modify requirements for civil penalty assessments, incidental boundary revisions and use of explosives.

OSMRE published a notice in the **Federal Register** on February 26, 1986, announcing receipt of the proposed program amendments and procedures for the public comment period and for requesting a public hearing on the substantive adequacy of the proposed amendments (51 FR 6751). The public comment period ended March 28, 1986. There was no request for a public hearing and the hearing scheduled for March 24, 1986, was not held.

### III. Director's Findings

The Director finds, in accordance with SMCRA and 30 CFR 732.15 and 732.17, that the program amendments submitted by Indiana on January 31, 1986, meet the requirements of SMCRA and 30 CFR Chapter VII. Only those areas of particular interest are discussed below in the specific findings. Discussion of only those provisions for which findings are made does not imply any deficiency in any provisions not discussed.

*Civil Penalties*

Indiana has amended 310 IAC 12-6-11 to provide that the regulatory authority shall assess a penalty for a violation which leads to a cessation order and for notices of violation assigned 31 points or more under the point system established in 310 IAC 12-6-12.5. The rule provides that the regulatory authority may assess a penalty for 30 points or less. Under the rule, a penalty of $5000 per day shall be assessed for mining without a permit, except under certain circumstances.

Indiana has amended 310 IAC 12-6-12 to establish the requirements for assigning points for penalties based on certain factors. The factors to be considered are: The permittee's history of violations at the particular operation (up to 30 points); the seriousness of the violation for which the penalty is being assessed (up to 15 points); the degree of the permittee's negligence or fault in the violation (up to 25 points); and degree of good faith determined from the permittee's efforts to abate the violation (up to negative 30 points).