(m) *Primary protective barrier for mammography x-ray systems.* For mammography x-ray systems manufactured after September 30, 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed $2.58X10^{-8}$ C/kg (0.1 mR) for each activation of the tube.

(4) Compliance for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

Dated: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–16835 Filed 7–1–99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308, 1312

[DEA–180F]

Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [(-)-Δ^9-(trans)-Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This is a final rule of the Deputy Administrator of the Drug Enforcement Administration (DEA) transferring a drug between schedules of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811. With the issuance of this final rule, the Deputy Administrator transfers from schedule II to schedule III of the CSA the drug containing synthetic dronabinol [(-)-Δ^9-(*trans*)-tetrahydrocannabinol] in sesame oil and encapsulated in soft gelatin capsules in a product approved by the Food and Drug Administration (FDA). This rule also designates this drug as a schedule III non-narcotic substance requiring an import/export permit. As a result of this rule, the regulatory controls and criminal sanctions of schedule III will be applicable to the manufacture, distribution, importation and exportation of this drug.

EFFECTIVE DATE: July 2, 1999.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, 202–307–7183.

SUPPLEMENTARY INFORMATION:

Background

Dronabinol is the United States Adopted Name (USAN) for the (-)-isomer of Δ^9-(*trans*)-tetrahydrocannabinol [(-)-Δ^9-(*trans*)-THC], which is believed to be the major psychoactive component of *Cannibas sativa L.* (marijuana). On May 31, 1985, FDA approved for marketing the product Marinol®—which contains synthetic dronabinol in sesame oil and encapsulated in soft gelatin capsules—for the treatment of nausea and vomiting associated with cancer chemotherapy. Following this FDA approval, DEA issued a final rule on May 13, 1986, transferring FDA-approved products of the same formulation as Marinol® from schedule I to schedule II of the CSA in accordance with 21 U.S.C. 811(a). (For simplicity within this document, the term ''Marinol®'' will be used hereafter to refer to Marinol® and any other products, which may by approved by FDA in the future, that have the same formulation as Marinol®.) The 1986 rescheduling of Marinol® was based on a medical and scientific evaluation and scheduling recommendation from the Assistant Secretary for Health in accordance with 21 U.S.C. 811(b). The transfer of Marinol® to schedule II did not affect the CSA classification of pure dronabinol, which—as a tetrahydrocannabinol with no currently accepted medical use in treatment in the United States—remains a schedule I controlled substance. On December 22, 1992, FDA expanded Marinol®'s indications to include the treatment of anorexia associated with weight loss in patients with AIDS.

The Petition To Reschedule Marinol®

On February 3, 1995, UNIMED Pharmaceuticals, Inc. petitioned the Administrator of DEA to transfer Marinol® from schedule II to schedule III. In response to this petition, and in view of supplemental information that UNIMED provided to DEA on December 11, 1996, DEA had to determine whether this proposed rescheduling of Marinol® would comport with United States obligations under the Convention on Psychotropic Substances, 1971 (Psychotropic Convention). See 21 U.S.C. 811(d). Under the Psychotropic Convention, dronabinol and all dronabinol-containing products, such as Marinol®, are listed in schedule II. As a result, the United States is obligated under the Psychotropic Convention to impose certain restrictions on the export and import of Marinol®. DEA has concluded that, in order for the United States to continue to meet its obligations under the Psychotropic Convention, DEA will continue to require import and export permits for international transactions involving Marinol®, even though Marinol® will be transferred to schedule III of the CSA. (As set forth below, to accomplish this, DEA is hereby amending 21 CFR 1312.30 to require import and export permits for international transactions involving Marinol®.)

After determining that Marinol® could be transferred to schedule III while maintaining the controls required by the Psychotropic Convention, and after gathering the necessary data, on August 7, 1997, DEA requested from the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), a scientific and medical evaluation, and recommendation, as to whether Marinol® should be rescheduled, in accordance with 21 U.S.C. 811(b).

On September 11, 1998, the Acting Assistant Secretary for Health sent to DEA a letter recommending that Marinol® be transferred from schedule II to schedule III of the CSA. Enclosed with the September 11, 1998, letter was a document prepared by the FDA entitled ''Basis for the Recommendation for Rescheduling Marinol® Capsules from schedule II to schedule III of the Controlled Substances Act (CSA).'' In this document, the FDA defines the Marinol® product as ''an FDA-approved drug product containing synthetically produced dronabinol dissolved in sesame oil and encapsulated in soft

gelatin capsules (2.5 mg, 5 mg, and 10 mg per dosage unit).'' The document contained a review of the factors which the CSA requires the Secretary to consider, which are set forth in 21 U.S.C. 811(c).

The Proposed Rule

On November 7, 1998, the then-Acting Deputy Administrator of DEA published a notice of proposed rule making in the **Federal Register** (63 FR 59751), proposing to transfer Marinol® from schedule II to schedule III of the CSA. The proposed rule was based on the DHHS scientific and medical evaluation and scheduling recommendation and DEA's independent evaluation. Also under the proposed rule, 21 CFR 1312.30 would be amended to include Marinol® as a schedule III non-narcotic controlled substance specifically designated as requiring import and export permits pursuant to 21 U.S.C. 952(b)(2) and 953(e)(3). As discussed above, this proposed amendment to 21 CFR 1312.30 is necessary for the United States to continue to meet its obligations under the Psychotropic Convention. The notice of proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing in writing to DEA on or before December 7, 1998.

Comments From the Public

DEA received comments regarding the proposed rule from ten persons. Nine of the commenters supported the proposed rule. One commenter objected to the proposed rule and requested a hearing thereon. The comments are briefly summarized below.

The nine commenters who supported the proposed rule included organizations, physicians, and one individual. Eight of the nine commenters who supported the proposed rule expressed the opinion that Marinol® is a safe and effective alternative to smoking marijuana for treatment of nausea and loss of appetite and has low abuse potential.

One commenter who supported the proposed rule expressed the view that the rescheduling of Marinol® should not serve as a substitute for making marijuana legally available for medical use. This commenter stated that it supported the use of marijuana for medical purposes and, therefore, wished to emphasize that the proposed rule affected the CSA status of Marinol®—not that of marijuana, which remains a schedule I controlled substance.

The one commenter who objected to the proposed rule, and requested a hearing thereon, asserted that Marinol® should not be transferred to schedule III unless and until marijuana and all other THC-containing drugs are simultaneously and likewise rescheduled. This commenter asserted that Marinol® has the same potential for abuse as marijuana and all other THC-containing drugs. This commenter agreed with the proposed rule that Marinol®'s potential for abuse is less than the ''high potential for abuse'' commensurate with schedules I and II of the CSA. Accordingly, this commenter agreed that Marinol® should be transferred to a less restrictive schedule than schedule II. However, this commenter disagreed with what would be the resultant status of Marinol® vis-á-vis marijuana and THC if the NPRM becomes final: Marinol® would be in schedule III while marijuana and THC would remain in schedule I. This commenter asserted that the CSA prohibited transferring Marinol® to a less restrictive schedule unless marijuana and all THC-containing drugs are simultaneously transferred to the same schedule. DEA has determined that this commenter's objections are based on a misinterpretation of the CSA, which can be addressed, as a matter of law, without conducting a fact-finding hearing. Accordingly, as this commenter presented no material issues of fact, DEA denied this commenter's request for a hearing.

Findings

Relying on the scientific and medical evaluation and scheduling recommendations of the Assistant Secretary for Health, and based on DEA's independent review thereof, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on information now available, Marinol® has a potential for abuse less than the drugs or other substances in schedules I and II.

(2) Marinol® is a FDA-approved drug product and has a currently accepted medical use in treatment in the United States; and

(3) Abuse of Marinol® may lead to moderate of low physical dependence or high psychological dependence.

Rescheduling Action

Based on the above findings, the Deputy Administrator of the DEA concludes that Marinol® should be transferred from schedule II to schedule III. Schedule III regulations will, among other things, allow five prescription refills in six months and lessen record keeping requirements and distribution restrictions. The schedule III control of Marinol® will become effective July 2, 1999, except that certain regulatory provisions governing registrants who handle Marinol will take effect as indicated below. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the schedule III regulations regarding Marinol®. The applicable regulations are as follows.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports Marinol® or who engages in research or conducts instructional activities with Marinol®, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* Marinol® must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All commercial containers of Marinol®, which are packaged on or after January 3, 2000 must have the appropriate Schedule III labeling as required by §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations. Commercial containers of Marinol® packaged before January 3, 2000. After April 3, 2000, all commercial containers of Marinol must bear the CIII labels as specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. *Inventory.* Registrants possessing Marinol® are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. *Records.* All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

6. *Prescriptions.* All prescriptions for Marinol® are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations. All prescriptions for Marinol® issued on or after July 2, 1999, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after January 2, 2000.

7. *Importation and Exportation.* Due to its international control status, import and export permits for Marinol® will be required in accordance with 21 CFR 1312.30. All importation and exportation of Marinol® shall be in compliance with part 1312 of Title 21 of the CFR.

8. *Criminal Liability.* Any activity with Marinol® not authorized by, or in violation of, the CSA or the Controlled

Substances Import and Export Act shall continue to be unlawful.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rule making ''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, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Marinol® is a prescription drug used to treat nausea due to cancer chemotherapy and AIDS wasting. Handlers of Marinol® are likely to handle other controlled substances used to treat cancer or AIDS which are already subject to the regulatory requirements of the CSA. Further, placement of Marinol® in schedule III of the CSA will mean a significant decrease in the regulatory requirements for persons handling Marinol®.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1308

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

21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Narcotics, Reporting requirements.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR parts 1308 and 1312 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) unless otherwise noted.

§ 1308.12 [Amended]

2. Section 1308.12 is amended by removing paragraph (f)(1) and redesignating the existing paragraph (f)(2) as (f)(1).

3. Section 1308.13 is amended by adding a new paragraph (g) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(g) *Hallucinogenic substances.*

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

(2) [Reserved]

PART 1312—[AMENDED]

1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 952, 953, 954, 957, 958.

2. Section 1312.30 is amended by adding a new paragraph (a) and reserving paragraph (b) to read as follows:

§ 1312.30 Schedule III, IV and V non-narcotic controlled substances requiring an import and export permit.

* * * * *

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

(b) [Reserved]

Dated: June 28, 1999.

Donnie R. Marshall,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 99–16833 Filed 7–1–99; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[LA–29–1–7403; FRL–6370–8]

Approval and Promulgation of Air Quality Implementation Plans; Louisiana: Reasonable-Further-Progress Plan for the 1996–1999 Period, Attainment Demonstration, Contingency Plan, Motor Vehicle Emission Budgets, and 1990 Emission Inventory for the Baton Rouge Ozone Nonattainment Area; Louisiana Point Source Banking Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, the EPA is finalizing its approval of revisions to the Louisiana State Implementation Plan (SIP) for the Baton Rouge ozone nonattainment area. These revisions were submitted by the State of Louisiana for the purpose of satisfying the Post-1996 Rate-of-Progress (ROP), Attainment Demonstration, and Contingency Plan requirements of the Federal Clean Air Act (the Act), which will aid in ensuring the attainment of the National Ambient Air Quality Standard (NAAQS) for ozone. The EPA is also approving the associated 1999 Motor Vehicle Emissions Budgets (MVEBs) for the area.

The EPA is also taking final action to approve additional SIP revisions submitted by Louisiana including codifying revisions that were made to the 1990 base year emission inventory and submitted to the EPA as part of the Baton Rouge 15% Rate-of-Progress Plan approved on October 22, 1996. Furthermore, the EPA is approving additional revisions to the 1990 base year emissions inventory submitted as part of the Post-1996 ROP Plan. The EPA is also approving the State's point source banking regulations. This rulemaking action is being taken under sections 110, 301, and part D of the Act.

EFFECTIVE DATE: This action is effective on August 2, 1999.