beyond all edges of the image receptor to ''within 2 percent of the SID'', discussed at 62 FR 55852 at 55945 of the regulation preamble was erroneously applied in the regulations only to the chest-wall side of the image receptor. This omission raises the possibility of an unnecessary radiation hazard to the patient if the x-ray field extends an excessive amount beyond the nonchest wall edges of the image receptor. The agency is proposing to remove the radiation hazard concern by amending § 900.12(e)(5)(vii)(A) to apply the 2 percent of the source-image receptor distance (SID) extension limit to all edges of the image receptor, in accordance with the intentions expressed in the preamble.

Finally, FDA is also proposing to simplify the regulations by dropping all mention of alignment from § 900.12(b)(5), thus consolidating all alignment requirements at one location in § 900.12(e)(5)(vii)(A). The portion of § 900.12(b)(5) dealing with the light field remains unchanged.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impact of this rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that this rule, if finalized, will not have a significant economic impact on a substantial number of small entities. This rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

FDA had previously estimated (62 FR 55852 at 55968) that the expected average annual benefits from the final regulations would range between $181.7 to $262.7 million. Average annual compliance costs were estimated at $38.2 million. The compliance cost estimate did not include the possible added costs related to the alignment requirement discussed previously, as the difficulty noted by the one manufacturer was not foreseen during the development of the regulations. These added costs would be minimal if an alternative requirement was applied for and received but would be more significant if retrofitting or purchasing of a new unit was carried out to meet the requirement. However, amending the regulations as proposed by FDA would eliminate the requirement leading to the possible extra costs and thus eliminate any possible extra cost.

V. Paperwork Reduction Act of 1995

The agency has tentatively determined that this proposed rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

2. Section 900.12 is amended by removing paragraph (b)(5)(i) and by redesignating paragraph (b)(5)(ii) as paragraph (b)(5), by revising newly redesignated paragraph (b)(5), and by revising paragraph (e)(5)(vii)(A) to read as follows:

§ 900.12 Quality standards.

* * * * *

(b) * * *

(5) *Light fields*. For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

* * * * *

(e) * * *

(5) * * *

(vii) * * *

(A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than two percent of the SID.

* * * * *

Dated: September 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29563 Filed 11–4–98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–180P]

21 CFR Parts 1308 and 1312

Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol (Martinol®; (-)-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: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) to remove the Food and Drug Administration (FDA) approved drug product containing dronabinol [Marinol®; (-)-Δ^9-(*trans*)-tetrahydrocannabinol in sesame oil and encapsulated in soft gelatin capsules] from Schedule II and place it into Schedule III of the Controlled Substances Act (CSA). This proposed action is based on an evaluation of the relevant data by the DEA and a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS)

that the FDA-approved dronabinol product [Marinol®; (-)-Δ^9-(*trans*)-THC in sesame oil and encapsulated in soft gelatin capsules] be rescheduled from Schedule II to Schedule III. If finalized, this action will impose the regulatory controls and criminal sanctions of Schedule III on those who handle dronabinol and products containing dronabinol.

DATES: Comments, objections and requests for a hearing must be received on or before December 7, 1998.

ADDRESSES: Comments, objections and requests for a hearing should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, DC. 20537; Attention: DEA Federal Register Representative/CCR.

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

SUPPLEMENTARY INFORMATION: Dronabinol is the synthetic equivalent of the (-)-isomer of Δ^9-(*trans*)-tetrahydrocannabinol [Δ^9-(*trans*)-THC], which is the major psychoactive component of *Cannabis sativa L.* (Marijuana). Dronabinol, under the trade name Marinol®. was approved for marketing by the FDA on May 31, 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. Dronabinol [Marinol®; (-)-Δ^9-(*trans*)-THC in sesame oil and encapsulated in soft gelatin capsules], but not THC itself, was transferred from Schedule I to Schedule II of the CSA on May 13, 1986, in accordance with 21 U.S.C. 811(a) and the FDA approval of a new drug application for Marinol® capsules. The rescheduling of Marinol® was based on a recommendation from the Assistant Secretary for Health which also stated that THC should remain in Schedule I. Marinol®'s indications were expanded on December 22, 1992 to include the treatment of anorexia associated with weight loss in patients with AIDS.

On February 3, 1995, UNIMED Pharmaceuticals, Inc. petitioned the Administrator of the DEA to reschedule dronabinol formulations from Schedule II to Schedule III. This request involves only dronabinol [synthetic (-)-Δ^9-(*trans*)-THC], specifically the product Marinol® (dronabinol in sesame oil in a soft gelatin capsule). Prior to a review of the data in the petition, the DEA had to determine whether the rescheduling of dronabinol formulations to Schedule III was possible, in light of the control of THC in Schedule II of the 1971 Convention on Psychotropic Substances. The DEA concluded that control of dronabinol formulations in Schedule III of the CSA was possible and would meet the requirements of Schedule II of the convention provided that THC remained in Schedule I or II of the CSA and that 21 CFR 1312.30 was amended to require import and export permits for international transactions involving dronabinol.

On December 11, 1996, UNIMED Pharmaceuticals, Inc. submitted a supplement to its petition to reschedule dronabinol formulations from Schedule II to Schedule III. This supplement provided data regarding the pharmacokinetics of Marinol®, additional data about the chemistry of the product and studies regarding the actual abuse of the Marinol® product. This information specifically addressed the criteria required to be considered under the CSA.

On August 7, 1997, after gathering the necessary data, the DEA sent its review document and a letter to the Acting Assistant Secretary for Health, DHHS requesting a scientific and medical evaluation of the available data and a scheduling recommendation on dronabinol, as required by 21 U.S.C. 811(b).

On September 11, 1998, the Acting Assistant Secretary for Health sent to the DEA a letter recommending that dronabinol (Marinol®; (-)-Δ^9-(trans)-THC in sesame oil and encapsulated in soft gelatin capsules) 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 CSA.'' In this document, the FDA defines the Marinol® product as ''an FDA approved drug product containing synthetically produced dranabinol 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 [21 U.S.C. 811(c)].

The factors considered by the Acting Assistant Secretary for Health and the DEA with respect to dranabinol were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the drug or other substance;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

The pharmacological and behavioral effects of dronabinol are comparable to those of Δ^9-THC, marijuana and other active cannabinoids. There are few scientific studies that directly evaluate the pharmacologeutical and behavioral effects of the product Marinol® to indicate that there are differences in its abuse liability compared to oral THC. Nevertheless, there is little evidence of actual abuse of Marinol®, despite modest annual increases in the total number of prescriptions written. Despite dronabinol's THC-like abuse liability, there are several factors that deter its actual abuse and trafficking. These factors include dronabinol's formulation in sesame oil, the improbability that the THC would be extracted from the product and abused by another route of administration, and its delayed onset of effects. Although excessive use of Marinol® may result in the development of psychological dependence, there has been no evidence of such use. The scientific data reviewed to date and the minimal evidence of actual abuse and trafficking support the transfer of dronabinol to Schedule III of the CSA.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health in accordance with section 201(b) of the CSA (21 U.S.C. 811(b)), and the independent review of the DEA, the Acting Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the CSA (21 U.S.C. 811(a) and 811(b)), finds that:

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

(2) Marinol® [(-)-Δ^9-(trans)-THC in sesame oil and encapsulated in soft gelatin capsules] is an FDA approved drug product and has a currently accepted medical use in treatment in the United States; and

(3) Abuse of dronabinol [Marinol®; (-)-Δ^9-(*trans*)-THC in seasame oil and encapsulated in soft gelatin capsules] may lead to moderate or low physical dependence or high psychological dependence.

Based on these findings, the Acting Deputy Administrator of the DEA concludes that dronabinol [Marinol®; (-)-Δ^9-(*trans*)-THC in sesame oil and encapsulated in soft gelatin capsules]

should be removed from Schedule II and placed into Schedule III of the CSA.

Special Provisions Regarding Import/Export Authorization

Dronabinol is internationally controlled in Schedule II of the 1971 Convention on Psychotropic Substances, to which the United States is a party. Under the special obligations of the Convention, Article 12 defines provisions relating to international trade relative to Schedule II substances. Specifically, signatory countries are required to issue import/export permits/authorizations to import or export a Schedule II substance. Due to its international control status, import/export permits for dronabinol still will be required despite the proposed transfer of dronabinol to Schedule III of the CSA.

In accordance with 21 CFR 1312.13(b) ''[t]he Administrator may require that such non-narcotic controlled substances in Schedule III as he shall designate by regulation in § 1312.30 of this part be imported only pursuant to the issuance of an import permit'' (21 U.S.C. 952(b)(2)). Similarly, the DEA could require export permits for Schedule III non-narcotic substances (21 CFR 1312.23(b) and 21 U.S.C. 953(e)(2)).

Currently, there are no Schedule III non-narcotic substances for which the Administrator requires an import/export permit. However, in accordance with 21 CFR 1312.30, this proposed designation of dronabinol as a Schedule III non-narcotic substance requiring an import/export permit is necessary for the United States to remain in compliance with the Convention.

Interested persons are invited to submit their comments, objections or requests for a hearing, in writing, with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Acting Deputy Administrator, Drug Enforcement Administrator, Washington, DC 20537. Attention: DEA Federal Register Representative/CCR. In the event that comments, objections, or requests for a hearing raise one or more issues which the Acting Deputy Administrator finds warrant a hearing, the Acting Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action 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, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Dronabinol products are prescription drugs used to treat nausea due to cancer chemotherapy and AIDS wasting. Handlers of dronabinol 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 dronabinol in Schedule III of the CSA will mean a significant decrease in the regulatory requirements for persons handling dronabinol products.

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 United States, on the relationship between the national government and the United 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 Federalism Assessment.

List of Subjects

21 CFR Part 1308

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

21 CFR Part 1213

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 Acting Deputy Administrator hereby proposes that 21 CFR parts 1308 and 1312 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) unless otherwise noted.

§ 1308.12 [Amended]

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

3. Section 1308.13 is proposed to be amended by adding a new paragraph (g)(1) 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: (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-[6H-dibenzo[b,d]pyran-1-ol] or (-)-delta-9-(trans)-tetrahydrocannabinol]

PART 1312—[AMENDED]

1. Section 1312.30 is proposed to be amended by adding a new paragraph (a) to read as follows:

§ 1313.30 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.

* * * * *

Dated: October 29, 1998.

Donnie R. Marshall,

Acting Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 98–29571 Filed 11–4–98; 8:45 am]

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