improve performance and health of birds challenged with *E. maxima*.

(3) *Limitations.* Feed continuously. Not for use in hens producing eggs for human food.

Dated: June 4, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–16836 Filed 7–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 98N–0877]

Medical Devices; Performance Standard for Diagnostic X–Ray Systems; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends the diagnostic x-ray systems performance standard for dental panoramic systems and mammography systems. This rule exempts panoramic dental x-ray units from the requirement that they be manufactured with exposure timers that automatically reset to zero upon premature termination of an exposure. Removing the automatic timer reset requirement will not compromise the quality of the radiographic image and will protect patients from being subject to unnecessary radiation due to repeat radiographs. This action also is intended to align the performance standard for mammography systems with the equipment requirements issued under the Mammography Quality Standards Act of 1992 (the MQSA).

EFFECTIVE DATE: September 30, 1999.

FOR FURTHER INFORMATION CONTACT: Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0865.

SUPPLEMENTARY INFORMATION:

I. Background

A. Panoramic Dental Radiograph

The requirements in § 1020.31 (21 CFR 1020.31) apply to diagnostic x-ray systems, including those used for dental radiography and mammography. Based on information from manufacturers, FDA had determined that the timer requirement in § 1020.31(a)(2)(i) should not apply to panoramic dental units. As a result of that determination, FDA exercised its enforcement discretion and did not apply the timer requirement to panoramic dental units. Some States had adopted local standards that were identical in language to FDA's regulation, but did not exempt panoramic dental units from the timer requirement because those units were not expressly exempted in the Federal regulation. Those States were applying the timer requirement to dental panoramic units. To correct this inconsistency, FDA has amended the regulations to expressly exempt panoramic dental units from the timer requirement in § 1020.31(a)(2)(i). This change should lead to consistency among government requirements.

B. Mammography X–Ray Devices

The recent passage of the MQSA (Pub. L. 102–539) and issuance of the interim and final MQSA regulations have focussed attention on the mammography equipment requirements contained in 21 CFR part 1020. Although the MQSA is directed to facility requirements for maintaining mammography quality, both the interim and the final MQSA regulations address x-ray equipment that is also subject to the performance standard for diagnostic x-ray systems (58 FR 67558 and 58 FR 67565, December 21, 1993; and 62 FR 55976, October 28, 1997). The MQSA and FDA's regulations governing mammography establish quality standards for facilities performing mammography to ensure safe, reliable, and accurate mammography nationwide. FDA wanted to ensure that the standards applying to radiation emitting electronic products, including mammography equipment, and those applying to the facilities that use such equipment were in accord. To bring the standards into harmony, FDA has amended its performance standard for diagnostic x-ray systems.

The MQSA standards also address the proper viewing of mammography films. The standard practice is that these films be read on view boxes (light boxes) with the ambient room light levels reduced. Unexposed film areas and parts of the light box not covered by exposed film should be masked to prevent the bright light surrounding the radiograph from interfering with reading the film.

Extending the x-ray field to expose the borders of the film simplifies the work of the radiologist and accreditation bodies because they have to create only one mask size, rather than having to create individualized masks for each facility. With the current practice being to irradiate the same area of the same sized film for all patients, there is little evidence that allowing the x-ray field to completely darken the film will significantly raise the radiation safety risk to the patient. FDA has amended the diagnostic x-ray systems standard to allow fixed aperture and variable aperture beam-limiting device (BLD) systems, to open up or adjust the field size to cover the entire film and thus reduce the need to provide a different mask for each film. In certain instances, limiting the x-ray field to the size of the breast may be considered to be advantageous. Practitioners still retain this option, which may result in improved imaging quality due to the reduction of scattered radiation.

To reduce unnecessary radiation exposure to the patient beyond the plane of the image receptor, FDA has requirements for x-ray field limitation and alignment. In the past, all systems in use for mammography had fixed aperture plates for x-ray field limitation. The advent of the variable aperture BLD for mammography is potentially a problem with respect to the primary barrier requirement if a BLD is opened so that the useful beam extends beyond the primary barrier provided by the image receptor support device. To prevent this problem, a variable aperture BLD must provide some restriction on the maximum field size to ensure that the entire useful beam at the plane of the image receptor is contained within the image receptor support device, which is also a primary barrier. In other words, for a fixed aperture or a variable aperture BLD with the collimator opened as wide as possible, the entire useful beam should not extend beyond the barrier, at any available source-image receptor distance (SID), except at the chest wall side, and the exposure level 5 centimeters beyond this barrier should not exceed 2.58×10^{-8} coulombs per kilogram (C/k) (0.1 milliroentgen (mR)) per exposure. This requirement is in agreement with the International Electrotechnical Commission (IEC) draft standard for mammography systems (IEC 62B/60601–2–45).

II. The Final Rule

FDA believes that the final rule establishes reasonable requirements that can be implemented by the regulated industry without unnecessary burden. None of the comments on the proposed rule requested that FDA revise any of the changes proposed.

A. Panoramic Dental Radiograph

The final rule exempts panoramic dental x-ray units from the requirement in § 1020.31(a)(2)(i) that they be

manufactured with exposure timers that automatically reset to zero upon premature termination of an exposure. This change incorporates into regulation current FDA policy and should lead to consistency among Federal, State, and local requirements.

B. Mammography X–Ray Devices

The MQSA requires that only x-ray equipment specifically designed for mammography can be used for mammography. Therefore, FDA has removed the reference in § 1020.31(f)(3), which allowed the use of general purpose x-ray equipment with special attachments for mammography. This change harmonizes this regulation with the MQSA equipment requirements.

Section 1020.31 permits the x-ray irradiation field at the plane of the image receptor to extend to the edges of the x-ray film. However, to protect the patient from unnecessary exposure to radiation, the mammographic field alignment requirement restricts the irradiation beam from extending beyond the edge of the receptor by no more than 2 percent of the SID. The limit on x-ray transmission through the primary barrier (except on the chest wall edge) remains unchanged. FDA has added the words ''for transmission'' to § 1020.31(m)(4) to further clarify the section.

The definition for ''image receptor support device'' replaces the definition of ''image receptor support'' and clarifies that image receptor support devices must provide a primary protective barrier for any orientation of the x-ray tube and the image receptor support device (except the chest wall side). This revision maintains the requirement in the current § 1020.31(m) that the image receptor support device must serve to provide a primary protective barrier that intercepts the useful beam. Equipment manufactured prior to the effective date of this rule has always been, and will continue to be, subject to the requirement that the primary barrier must intercept the useful beam.

Unlike fixed aperture systems, which meet the established primary barrier requirement, with variable aperture collimation there is the possibility that the dimensions of the x-ray beam may be adjusted to exceed the area of the image receptor. This requirement confines the x-ray beam to the dimensions of the primary barrier provided by the image receptor support device, except on the chest wall side.

FDA has clarified the requirement that patient exposures not be permitted without an appropriate primary barrier in place, by stating the requirement explicitly. FDA further clarifies the requirement by adding the word appropriate prior to primary barrier. FDA wants to clarify that it is not appropriate for a mammographic x-ray system to generate x-rays with an inappropriate image receptor support device in place. To reduce radiation exposure to the patient, the rule provides that the image receptor support device, acting as the primary barrier, must be in place before a mammographic x-ray system can generate x-rays. This requirement requires the image receptor support device be interlocked with the system so that an exposure cannot be made with the image receptor support device removed.

C. Effective Date

This rule will be effective in 90 days. Usually, amendments to performance standards for electronic products become effective 1 year after the date of publication of the final rule to allow sufficient time for manufacturers to implement the changes in design or production practices (21 U.S.C. 360kk(c)). In the proposed rule, FDA explained its good cause basis for proposing a shorter timeframe, namely that the amendments were codifying current industry practice, making regulatory requirements consistent, or relaxing requirements, and requested comments on the proposed shortening of the timeframe. No comments were received. Consequently, this rule becomes effective September 30, 1999.

III. The Proposed Rule

In the **Federal Register** of October 29, 1998 (63 FR 57957), FDA published a proposed rule to amend the performance standard for diagnostic x-ray systems (dental and mammographic systems requirements). The proposed rule contained the reasons for the proposed amendment, summarized the Technical Electronic Product Radiation Safety Standards Committee's recommendation regarding dental and mammographic systems, and delineated the statutory authority under which FDA issues this rule. The proposed rule also stated FDA's grounds showing good cause for prescribing an earlier effective date than 1 year after the date of publication of the final rule for these amendments to the performance standard and solicited specific comment on the timeframe for implementation of the final rule. Written comments were due January 27, 1999.

FDA received three comments, one each from a manufacturer, a professional society, and a State agency. All three comments supported the actions proposed in the rule. None of the comments commented on the timeframe for implementation of the final rule.

IV. Response to Comments

All three comments supported the actions proposed in the rule. One of the comments requested clarification concerning § 1020.31(m)(2), which would require that the x-ray tube shall not permit exposure unless the barrier is in place to intercept the useful beam. The concern was whether the manufacturer would be held responsible if an individual equipment owner chose to partially dismantle the system or bypass interlocks so that the x-ray tube could be operated with the primary barrier removed. The comment stated that such action would violate § 1020.30(q)(2), which prohibits the owner of the equipment from modifying the equipment such that it would no longer comply with § 1020.31. In such a case, the comment argued that FDA should cite the owner, not the manufacturer, for noncompliance.

FDA agrees that a manufacturer should not be held responsible should an owner circumvent the interlocks to operate the system with the primary barrier removed. The regulation does not require the manufacturer to design an interlock that cannot be defeated. A modification by the owner that makes the unit noncompliant with §§ 1020.31(m)(2) and 1020.30(q) may cause the device to be misbranded and adulterated. FDA could bring an action against the person who caused the misbranding and adulteration and also seek to enjoin use of the device.

None of the comments include any recommendations on the timeframe for implementation of the final rule or suggest that FDA does not have good cause for shortening the customary 1-year period. FDA believes that unneeded delay in the implementation of these amendments could lead to difficulties for mammography facilities because of confusion over the requirements of the x-ray performance standard and standards issued under the MQSA. In addition, because the amendments clarify a provision of the Federal standard, FDA believes it is in the best interests of patients, facilities, and manufacturers to implement the dental x-ray equipment amendment expeditiously. For these reasons, the effective date of the final rule will be 90 days after date of publication in the **Federal Register**.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(a) and (i) and 25.34(c) 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.

VI. Analysis of Impacts

FDA has examined the impact of this final 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 this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and therefore 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. Because this final rule increases the flexibility of the performance standard and codifies current interpretations of Federal regulations in order to prevent inconsistent interpretations by State and local governments, and because none of the domestic manufacturers of panoramic dental units or mammography x-ray systems would be considered small entities, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities engaged in manufacturing. Because dental and mammography facilities will buy machines with the changes to the performance standard allowed in this final rule only if it is economically advantageous to do so, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities that are facilities (most, if not all, of which would be considered small entities). Therefore, under the Regulatory Flexibility Act, no further analysis is required.

In the proposed rule, FDA conducted and published an initial regulatory flexibility analysis to ensure that impacts on small entities were assessed and to alert any potentially impacted entities to the opportunity to submit comments to this agency. No comments on the initial regulatory flexibility analysis were submitted. This final rule will not impose costs of $100 million or more in either the private sector or State, local, and tribal governments in the aggregate. Consequently, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

In part, the final rule codifies the equipment performance standards established under the MQSA by requiring only x-ray systems designed specifically for mammography be marketed for mammography. This rule updates the x-ray performance standard to reflect a standard already enforced under the MQSA. Consequently, FDA expects no economic impact from this portion of the final rule.

The final rule also permits the x-ray irradiation field to extend to the edges of the x-ray film but not beyond the primary barrier provided by the image receptor support device. It further changes the definition of an image receptor support device, clarifying that it must provide a primary protective barrier and that exposures not be possible without the image receptor support device being in place, acting as the primary barrier. Exposing all of the film allows one size of film mask to be used for proper viewing of mammography films using light boxes and prohibiting extension of the beam beyond the primary barrier protects the patient from unnecessary exposure to radiation. The amendment to relax the field edge alignment criteria will not require any changes to x-ray mammography systems that are currently compliant; these systems will remain compliant after the effective date. The amendment will, however, allow the user to modify or purchase a collimator that has the ability to provide films without light borders as a convenience in simplifying viewing conditions. FDA believes that most of the image receptor support devices that are currently in use meet the requirements in the amendments to §§ 1020.30(b) and 1020.31(m). In addition, when the manufacturer's design of the cassette holder provides the primary barrier attenuation itself, then the cassette holder is considered a part of the image receptor support device. Therefore, FDA estimates that the amendments to §§ 1020.30(b) and 1020.31(m) will impose minimal new costs. This rule also allows more flexibility for mammography facilities and accreditation bodies without compromising the public health and may reduce costs to mammography facilities and accreditation bodies by simplifying the masking of images.

The final rule exempts panoramic x-ray dental units from the requirement that they be manufactured with exposure timers that automatically reset to zero or the initial setting upon premature termination of an exposure. For panoramic dental exposures, interrupting the exposure does not affect the quality of images already taken. Consequently, restarting the exposure at the initial starting point exposes patients to unnecessary radiation. This rule removes a regulatory requirement, while still protecting the public health, and may reduce costs to dental facilities and patients. FDA has identified no new reporting, recordkeeping, or other compliance requirements associated with this rule.

The Safe Medical Devices Act of 1990 (Pub. L. 101–629) enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the Public Health Service Act (42 U.S.C. 201 *et seq.*) to Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 *et seq.*). These provisions regulate electronic products that emit radiation. On October 27, 1992, the MQSA was enacted to establish uniform, national quality standards for mammography. The MQSA (42 U.S.C. 263b(f)(1)(B)) requires the use of radiological equipment specifically designed for mammography to be used for mammography. Similarly, 21 CFR 900.12(b)(1) of the interim and final mammography regulations prohibits the use of conventional radiographic equipment for mammography.

There are approximately 10,000 mammography facilities in the United States. Because this change in the performance standard only applies to components manufactured after the effective date of the final rule, the associated cost does not apply to those machines manufactured prior to that date. FDA estimates that approximately 10 percent of facilities replace their mammography machines in any one year. At this time, FDA is unable to estimate the demand for the modifications to systems currently in use. As discussed previously, the change concerning x-ray beam collimation is less restrictive than the present standard. FDA estimates the cost per system to be between $0 and $5,000, if the system modification is made during production.

There are approximately 138,500 dental facilities in the United States of

which 40 percent provide access to panoramic dental x-ray units. An uncertain number of these facilities may request the manufacturer to remove the automatic reset of the exposure timer on their panoramic machines; however, they are not required to do so. FDA believes that the facility will only make this change if it is economically or clinically advantageous to do so. FDA estimates it will cost a facility an amount equal to what would be assessed for a routine service call (approximately $150.00 or less) to remove the automatic reset function for premature termination of an exposure for existing systems. FDA believes that manufacturers no longer manufacture panoramic dental x-ray units with automatic reset exposure times.

Most, if not all, of the mammography facilities and dental facilities would be considered small under the criteria establishment by the Small Business Administration. FDA's registration system shows five manufacturers of panoramic dental units. Of the domestic manufacturers, none would be considered small entities. There are approximately 10 manufacturers of mammography x-ray systems. Of these manufacturers, none would be considered small entities.

For the mandatory changes to image receptor support devices, FDA believes that most of the image receptor support devices that are currently in use provide a primary barrier that is capable of meeting the requirements in the amendments to §§ 1020.30(b) and 1020.31(m). There are approximately 10,000 mammography facilities in the United States. Because this change in the performance standard only applies to systems manufactured after the effective date of a final rule, the costs associated with any changes that may need to be made, would not apply to those machines manufactured prior to that date. FDA estimates that approximately 10 percent of facilities replace their mammography systems in any one year (10 percent of 10,000 = 1,000). FDA estimates the cost per system to be between $0 and $2,000 in the event that any manufacturers are required to implement design or production changes to ensure that exposures not be permitted on their systems without a primary barrier being in place. FDA estimates approximately 95 percent of systems currently being marketed already meet this requirement. With an annual mammography system replacement rate of 10 percent (i.e., 1,000 new systems purchased per year), FDA estimates only approximately 5 percent of these 1,000 systems may increase the cost to meet the requirement. To calculate the annual cost, FDA estimates a cost of $0 to $2,000 per system multiplied by 50 systems (5 percent of 1,000 = 50). Using this estimate, the costs are expected to be approximately $0 to $100,000.

Under these changes to the performance standard, FDA allows manufacturers and facilities to decide whether to implement any device modifications in response to the greater flexibility in these mammography collimation requirements. If the benefits associated with the flexibility in this rulemaking are outweighed by the costs to the facility, the facility can choose to not purchase a device that has been modified in response to the greater flexibility in this rulemaking. With regard to the mandatory change, FDA believes that the great majority of the image receptor support devices that are currently being manufactured provide a primary barrier that is capable of meeting the requirements in the amendment to § 1020.31(m). Therefore, FDA does not anticipate that the amendment to § 1020.31(m) will impose any significant costs.

Because most of these changes to the mammography performance standard and the change to the timer requirement for panoramic dental systems do not increase regulatory burdens, FDA considered no alternatives to accomplish the stated objectives of the applicable statutes. For the primary barrier standard in § 1020.31(m), FDA considered not requiring the primary barrier to be in place to intercept the useful beam. This alternative was rejected because without the primary barrier in place, patients would be exposed to unnecessary radiation.

VII. Paperwork Reduction Act of 1995

This final rule contains no 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 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, 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 1020 is amended as follows:

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

1. The authority citation for 21 CFR part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360gg–360ss, 371, 381.

2. Section 1020.30 is amended in paragraph (b) by removing the definition of ''image receptor support'' and adding a new definition in alphabetical order to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(b) * * *

Image receptor support device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

* * * * *

3. Section 1020.31 is amended by revising paragraphs (a)(2)(i), (f)(3), and (m) to read as follows:

§ 1020.31 Radiographic equipment.

* * * * *

(a) * * *

(2) * * *

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

* * * * *

(f) * * *

(3) *Systems designed for mammography.* (i) Mammographic beam-limiting devices manufactured after September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Each image receptor support device intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

* * * * *

(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]

BILLING CODE 4160–01–F

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