this section of the preamble, we will refer to the proposed rule as a "proposed amendment." These findings are discussed below.

The amendment to the Standard is needed to adequately protect the public against unreasonable risk of the occurrence of fire. The current Standard specifies as the ignition source cigarettes that are no longer being produced. In order for the Standard to continue to be effective (and for labs to test mattresses and mattress pads to determine whether they comply with the Standard), it is necessary to change the ignition source specification. The proposed amendment is necessary to ensure that the testing is reliable and that results will not vary from one lab or manufacturer to another. Such variation would be likely if labs or manufacturers were able to use different ignition sources that have similar physical properties but different burning characteristics.

The amendment to the Standard is reasonable, technologically practicable, and appropriate. The proposed amendment is based on technical research conducted by NIST, which established that the SRM cigarette is capable of providing reliable and reproducible results in flammability testing of mattresses and mattress pads. The proposed SRM represents an equivalent, safety-neutral ignition source for use in testing to establish compliance with the Standard.

The amendment to the Standard is limited to fabrics, related materials, and products that present an unreasonable risk. The proposed amendment would continue to apply to the same products as the existing Standard.

Voluntary standards. There is no applicable voluntary standard for mattresses. The proposal would amend an existing Federal mandatory standard.

Relationship of benefits to costs. Amending the Standard to specify SRM cigarettes as the ignition source would allow testing to the Standard to continue without interruption, would maintain the effectiveness of the Standard, and would not significantly increase testing costs to manufacturers and importers of mattresses and mattress pads. Thus, there is a reasonable relationship between benefits and costs of the proposed amendment. Both expected benefits and costs of the proposed amendment are likely to be small. The likely effect on testing costs would be minor.

Least burdensome requirement. No other alternative would allow the Standard's level of safety and effectiveness to continue. Thus, the proposed amendment imposes the least burdensome requirement that would adequately address the risk of injury.

J. Conclusion

For the reasons discussed above, the Commission preliminarily finds that amending the mattress flammability standard (16 CFR part 1632) to specify SRM cigarettes as the ignition source is needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, injury, and significant property damage. The Commission also preliminarily finds that the amendment to the Standard is reasonable, technologically practicable, and appropriate. The Commission further finds that the amendment is limited to the fabrics, related materials, and products that present such unreasonable risks.

K. References

1. Gann, R.G., and Hnetkovsky E.J., *Modification of ASTM E 2187 for Measuring the Ignition Propensity of Conventional Cigarettes,* Technical Note 1627, National Institute of Standards and Technology, Gaithersburg, MD 20899, 2009.

2. Directorate for Economic Analysis Report, *Preliminary Regulatory Analysis: Smoldering Ignition Source Draft Proposed Technical Amendment to the Flammability Standard for Mattresses and Mattress Pads* (16 CFR part 1632).

List of Subjects in 16 CFR Part 1632

Consumer protection, Flammable materials, Labeling, Mattresses and mattress pads, Records, Textiles, Warranties.

For the reasons given above, the Commission proposes to amend 16 CFR part 1632 as follows:

PART 1632—STANDARD FOR THE FLAMMABILITY OF MATTRESSES AND MATTRESS PADS (FF 4–72, AMENDED)

1. The authority citation for part 1632 continues to read as follows:

Authority: 15 U.S.C. 1193, 1194; 15 U.S.C. 2079(b).

2. Section 1632.4 is amended by revising paragraph (a)(2) to read as follows:

§ 1632.4 Mattress test procedure.

(a) * * *

(2) *Ignition source.* The ignition source shall be National Institute of Standards and Technology ("NIST") Standard Reference Material ("SRM") 1196, available for purchase from the National Institute for Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899.

* * * * *

Dated: October 26, 2010.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2010–27504 Filed 10–29–10; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–344P]

Listing of Approved Drug Products Containing Dronabinol in Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to modify the listing of the Marinol® formulation in schedule III so that certain generic drug products are also included in that listing.

Several products are currently the subject of Abbreviated New Drug Applications (ANDAs) under review by the U.S. Food and Drug Administration (FDA). Each product is a generic formulation of Marinol® and contains dronabinol, the (-) isomer of delta-9-(trans)-tetrahydrocannabinol (THC), which is a schedule I controlled substance. Due to variations in formulation, these generic Marinol® products do not meet the specific conditions specified in the current schedule III listing.

This proposed action expands the schedule III listing to include formulations having naturally-derived dronabinol and products encapsulated in hard gelatin capsules. This would have the effect of transferring the FDA-approved versions of such generic Marinol® products from schedule I to schedule III.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before January 3, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–344" on all written and electronic correspondence. Written comments sent via regular or express

mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern Time on the day the comment period closes. Commenters in time zones other than Eastern Time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

The DEA has received four petitions from companies that have products that are currently the subject of ANDAs under review by the FDA. Each product is a generic formulation of Marinol® and contains dronabinol, the (-) isomer of delta-9-(trans)-tetrahydrocannabinol (THC), which is a schedule I controlled substance. These petitions each requests amendments to Controlled Substances Act (CSA) regulations that would have the effect of transferring the proposed generic Marinol® product from schedule I to schedule III.

At present, the only formulation containing dronabinol that is in a schedule other than schedule I is the following, as set forth in 21 CFR 1308.13(g)(1) as schedule III:

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

While the petitioners cite that their generic products are bioequivalent to Marinol®, their products do not meet schedule III current definition provided above. Therefore, these firms have requested that 21 CFR 1308.13(g)(1) be expanded to include: (1) Both naturally-derived or synthetically produced dronabinol; and (2) both hard or soft gelatin capsules.

In response to these petitions, DEA prepared several scheduling review documents based upon petitioner-provided data. On June 22, 2007, and August 15, 2007, these analyses were submitted to the Department of Health and Human Services (DHHS) with requests for scientific and medical evaluation and scheduling recommendations. The submissions to DHHS also requested that they consider (1) whether dronabinol extracted from Cannabis sativa (i.e. naturally-derived), is identical to synthetically-produced dronabinol found in Marinol®; and (2) whether a formulation encapsulated in hard gelatin capsules, instead of soft gelatin capsules, changes a product's abuse potential.

On March 17, 2010, and June 1, 2010, the Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA scientific and medical evaluations and letters recommending that FDA-approved drug products containing dronabinol (both naturally-derived or synthetic) in sesame oil in a gelatin capsule (either hard or soft gelatin) be placed into schedule III of the CSA. Enclosed with the March 17, 2010, letter, was a document prepared by the FDA entitled, "Basis for the Recommendation to Control FDA-Approved Drug Products Containing Synthetic Dronabinol in Sesame Oil in a Hard Gelatin Capsule to Schedule III of the Controlled Substances Act." The June 1, 2010, letter included a document entitled, "Basis for the Recommendation to Reschedule FDA-Approved Drug Products Containing Naturally-Derived Dronabinol in Sesame Oil in a Gelatin Capsule to Schedule III of the Controlled Substances Act." These documents contained a review of the factors which the CSA requires the Secretary to consider 21 U.S.C. 811(b).

Therefore, in this rulemaking, DEA is proposing that 21 CFR 1308.13(g)(1) be modified to include generic equivalents of Marinol® which are (1) both synthetic or naturally-derived dronabinol; and/or (2) hard or soft gelatin capsules.

Background Regarding Dronabinol

Dronabinol is a name of a particular isomer of a class of chemicals known as tetrahydrocannabinols (THC). Specifically, dronabinol is the United States Adopted Name (USAN) for the (-)-isomer of [Delta]\9\-(trans)-tetrahydrocannabinol [(-)-[Delta]\9\-(trans)-THC], which is believed to be the major psychoactive component of the cannabis plant (marijuana).

THC, as a general category, is listed in schedule I of the CSA,[1] while

[1] 21 U.S.C. 812(c), Schedule I(c)(17). Schedule I contains those controlled substances with "no currently accepted medical use in treatment in the

Continued

dronabinol contained in the product Marinol® is listed separately in schedule III. Any other formulation containing dronabinol (or any other isomer of THC), that does not meet the definition provided in 21 CFR 1308.13(g)(1), remains a schedule I controlled substance.[2]

The current wording of the Marinol® formulation in schedule III (21 CFR 1308.13(g)(1)) was added to the DEA regulations in 1986, when the substance was transferred from schedule I to schedule II after the FDA approved Marinol® for marketing.[3] The wording of this listing was not specific to Marinol® and thereby could include any generic product meeting that description that might be approved by the FDA in the future. However, at the time the regulation was promulgated, DEA did not anticipate the possibility that a generic formulation could be developed that did not fit precisely the wording of the listing that currently appears in schedule III.

Recently, firms have submitted to FDA ANDAs for their proposed generic versions of Marinol®. As these ANDAs remain pending with the FDA, the precise nature of these formulations is not available for public disclosure. However, these formulations might differ from the Marinol® formulation currently listed in schedule III. Nonetheless, the firms that have submitted the ANDAs assert that their formulations would meet the approval requirements under 21 U.S.C. 355(j), because, among other things, they have the same active ingredient, strength, dosage form, and route of administration as Marinol®, and are bioequivalent to Marinol®.

Products are bioequivalent if there is no significant difference in the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action 21 CFR 320.1. There is no requirement under 21 U.S.C. 355(j), or FDA's implementing regulations, that solid oral dosage forms such as capsules that are proposed for approval in ANDAs contain the same inactive ingredients as the listed drug referenced. The generic drug, therefore, would not fall within the scope of the current regulation. This situation, in which a generic version of a drug would not necessarily fall within the schedule for the referenced listed drug, is unique among the CSA schedules in the following respect. The Marinol® formulation listed in schedule III is the only listing in the schedules that has the effect of excluding potential generic versions of the brand name formulation.[4] As indicated above, this came about because DEA did not anticipate that other drug products could be approved by FDA that did not fit the description that was included in the schedules. Moreover, Congress structured the CSA so that there would be no distinction—for scheduling purposes—between brand name drug products and their generic equivalents. The rule being proposed here would ensure that this aspect of the CSA holds true for generic drug products approved under 21 U.S.C. 355(j) that reference Marinol® as the listed drug.

In addition, 21 U.S.C. 355(j)(2)(C) permits applicants to petition FDA for approval of an ANDA for a drug product that may differ from the listed drug in certain specified ways, if clinical studies are not necessary to establish the safety and effectiveness of the drug product. Among the types of differences permitted is a change in dosage form, or manner in which the active ingredient is produced.

This proposed rule would amend the description in schedule III [21 CFR 1308.13(g)(1)] to include products referencing Marinol® that are either (1) naturally derived or synthetic; or (2) in hard or soft gelatin capsules, as long as the formulations otherwise meet the approval requirements in 21 U.S.C. 355(j).

The CSA Scheduling Structure

To understand the legal justification for the rule being proposed here, the scheduling scheme established by Congress under the CSA must first be considered. One court has succinctly summarized this scheme as follows:

> The [CSA] sets forth initial schedules of drugs and controlled substances in 21 U.S.C. 812(c). However, Congress established procedures for adding or removing substances from the schedules (control or decontrol), or to transfer a drug or substance between schedules (reschedule). 21 U.S.C. 811(a). This responsibility is assigned to the Attorney General in consultation with the Secretary of Health and Human Services ("HHS") Id. Sec. 811(b). The Attorney General has delegated his functions to the Administrator of the DEA 28 CFR 0.100(b). Current schedules are published at 21 CFR 1308.11–1308.15.
>
> There are three methods by which the DEA may initiate rulemaking proceedings to revise the schedules: (1) By the DEA's own motion; (2) at the request of DHHS; (3) on the petition of any interested party. 21 U.S.C. 811(a);
>
> 21 CFR 1308.43(a). Before initiating rulemaking proceedings, the DEA must request a scientific and medical evaluation from DHHS and a scheduling recommendation. The statute requires the DEA and DHHS to consider eight factors with respect to the drug or controlled substance. 21 U.S.C. 811(b), (c).
>
> These factors are:
>
> (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.
>
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.
>
> Although the recommendations of DHHS are binding on the DEA as to scientific and medical considerations involved in the eight-factor test, the ultimate decision as to whether to initiate rulemaking proceedings to reschedule a controlled substance is made by the DEA.[5]
>
> Gettman v. DEA, 290 F.3d 430, 432 (DC Cir. 2002).

The FDA plays an important role within DHHS in the development of the DHHS scientific and medical determinations that bear on eight-factor analyses referred to above (required under section 811(c) for scheduling decisions). Thus, when it comes to newly developed drug products that contain controlled substances, FDA makes scientific and medical determinations for purposes of both the Food Drug and Cosmetic Act (in connection with decisions on whether to approve drugs for marketing) and the CSA (in connection with scheduling decisions). As explained below, the eight-factor analysis can be expected to yield the same conclusions with respect to a brand name drug product and certain generic drugs referencing that product that meet the approval requirements under 21 U.S.C. 355(j).

United States" and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).

[2] The introductory language to schedule I(c) states that any material, compound, mixture, or preparation that contains any of the substances listed in schedule I(c) (including "tetrahydrocannabinols") is a schedule I controlled substance "[u]nless specifically excepted or unless listed in another schedule." The only material, compound, mixture, or preparation that contains THC but is listed in another schedule is the Marinol® formulation, which is listed in schedule III.

[3] 51 FR 17476 (May 13, 1986). DEA subsequently transferred the FDA-approved Marinol® formulation from schedule II to schedule III. 64 FR 35928 (July 2, 1999).

[4] Generally, substances are listed in the CSA schedules based on their chemical classification, rather than any drug product formulation in which they might appear. Because of this, there have been no other situations in which a slight variation between the brand name drug formulation and the generic drug formulation was consequential for scheduling purposes.

[5] *See id.* Sec. 811(a), (b).

The ANDA Approval Process

The Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Amendments"), codified at 21 U.S.C. 355, 360cc, and 35 U.S.C. 156, 271, 282, permits the submission of ANDAs for approval of generic versions of approved drug products. 21 U.S.C. 355(j). The ANDA process shortens the time and effort needed for approval by, among other things, allowing the applicant to demonstrate its product's bioequivalence to a drug already approved under a New Drug Application (NDA) (the "listed" drug) rather than having to reproduce the safety and effectiveness data for that drug. If an ANDA applicant establishes that its proposed drug product has the same active ingredient, strength, dosage form, route of administration, labeling, and conditions of use as a listed drug, and that it is bioequivalent to that drug, the applicant can rely on FDA's previous finding that the listed drug is safe and effective [*See id*].[6] Once approved, an ANDA sponsor may manufacture and market the generic drug to provide a safe, effective, and low cost alternative to the American public.

The majority of drugs approved under 21 U.S.C. 355(j) are therapeutically equivalent to the listed drug they reference. This means that the generic drug and the referenced innovator drug contain identical amounts of the active ingredient, and are bioequivalent. Therapeutic equivalents can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

The key point, for purposes of the rule being proposed here, is that the generic drug can be substituted for the innovator drug with the full expectation that the generic drug will produce the same clinical effect and safety profile as the innovator drug. Consequently, for CSA scheduling purposes, the eight-factor analysis conducted by the FDA and DEA under 21 U.S.C. 811(c) would necessarily result in the same scheduling determination for an approved generic drug product as for the innovator drug to which the generic drug is a therapeutic equivalent. This is because, in conducting the eight-factor analysis, the FDA and DEA would be examining precisely the same medical, scientific, and abuse data for the generic drug product as would be considered for the innovator drug. The same would be true of the innovator drug and a drug product approved pursuant to a petition under 21 U.S.C. 355(j)(2)(C), where the drug approved in the ANDA differs from the listed drug only because it is a hard gelatin capsule and the listed drug is a soft gelatin capsule; or the active ingredient is naturally-derived, rather than synthetically produced.

As noted earlier, these considerations never previously arose for any other controlled substance because the regulation citing the Marinol® formulation is the only scheduling regulation that is drug product formulation-specific and thereby (inadvertently) excludes certain generic versions.[7] This unintended result is not consistent with the structure and purposes of the CSA, which generally lists categories of substances in the schedules, rather than product formulations. Thus, by ensuring that generic versions of the Marinol® formulation which might be approved by the FDA in the future are in the same schedule as Marinol®, the rule being proposed here would make the DEA regulations more consistent with the structure and purposes of the CSA.

Finally, for additional clarity, the proposed rule would amend 21 CFR 1308.13(g)(1) to change the phrase "U.S. Food and Drug Administration approved product" to "drug product approved for marketing by the U.S. Food and Drug Administration."

On June 22, 2007, and August 15, 2007, DEA submitted scheduling review documents for several dronabinol generic products to the DHHS, and requested that DHHS provide scientific and medical evaluation and scheduling recommendations under the CSA. (These documents are available for review online at *http://www.deadiversion.usdoj.gov*.)

On March 17, 2010, and June 1, 2010, the Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA scientific and medical evaluations and letters recommending that FDA-approved drug products containing dronabinol (naturally-derived or synthetic) in sesame oil in a gelatin capsule (hard or soft) be placed into schedule III of the CSA. Enclosed with the March 17, 2010, letter was a document prepared by the FDA entitled, "Basis for the Recommendation to Control FDA-Approved Drug Products Containing Synthetic Dronabinol in Sesame Oil in a Hard Gelatin Capsule to Schedule III of the Controlled Substances Act." The June 1, 2010 letter included a document entitled, "Basis for the Recommendation to Reschedule FDA-Approved Drug Products Containing Naturally-Derived Dronabinol in Sesame Oil in a Gelatin Capsule to Schedule III of the Controlled Substances Act." These documents contained a review of the factors which the CSA requires the Secretary to consider. 21 U.S.C. 811(b).

Note: The DHHS scheduling recommendations of March 17, 2010, and June 1, 2010, are available for review online at *http://www.deadiversion.usdoj.gov*.

The factors considered by the Assistant Secretary of Health and DEA with respect to these products were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects;

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

(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. 21 U.S.C. 811(c).

The DHHS scheduling recommendation of March 17, 2010, concluded that drug products containing synthetic dronabinol in sesame oil and encapsulated in a hard gelatin capsule, have a similar potential for abuse as Marinol®. "These products contain the same Active Pharmaceutical Ingredient (API), have similar chemistry and pharmacokinetics and have similar formulations in sesame oil." FDA and National Institute on Drug Abuse (NIDA), after reviewing the available information conclude "that drug products approved for marketing by FDA that contain synthetic dronabinol in sesame oil in a hard gelatin capsule be controlled in Schedule III of the CSA."

The DHHS scheduling recommendation of June 1, 2010, concluded that drug products that contain naturally-derived dronabinol in sesame oil and in a gelatin capsule, have a similar potential for abuse as Marinol®. FDA and NIDA, after reviewing the available information, concluded "that drug products approved

[6] *See* also Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), Intro. at p. vi, (27th ed.).

[7] When Congress enacted the CSA in 1970, it scheduled codeine and certain other opiates in three different schedules depending on their respective concentrations. *See* 21 U.S.C. 812(c), schedule II(a)(1), schedule III(d), and schedule V. However, this differential scheduling for opiates does not specify drug product formulation in a manner that would result in a generic version of an opiate drug product being scheduled separately from the innovator drug.

for marketing by FDA that contain naturally-derived dronabinol in sesame oil in a gelatin capsule should be rescheduled to Schedule III of the CSA."

Based on the recommendations of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act [21 U.S.C. 811(b)], and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act [21 U.S.C. 811(a) and 811(b)], finds that FDA-approved generic dronabinol products, both naturally-derived or synthetically produced, in sesame oil and encapsulated in both hard gelatin or soft gelatin capsules meet the criteria for placement in schedule III set in 21 U.S.C. 812(b), as follows:

A. The Drug or Other Substance Has a Potential for Abuse Less Than the Drugs or Other Substances in Schedule II

FDA-approved generic drug products that contain dronabinol (both naturally-derived or synthetically produced) in sesame oil in a gelatin capsule (both hard or soft gelatin) and reference Marinol®, have a similar potential for abuse as Marinol®, a schedule III drug product and have similar chemistry and pharmacokinetics as similar formulations in sesame oil.

B. The Drug or Other Substance Has a Currently Accepted Medical Use in Treatment in the United States

Marinol® was initially approved by FDA in 1985. When drug products that reference Marinol® receive FDA approval, they will have a currently accepted medical use in the United States.

C. Abuse of the Drug or Other Substance May Lead to Moderate or Low Physical Dependence or Psychological Dependence and Such Dependence Would Be Less Than the Drugs or Other Substances in Schedule II

The withdrawal syndrome associated with dronabinol, the API in Marinol®, produces symptoms in humans such as restlessness, irritability, mild agitation, anxiety, anger, insomnia, sleep EEG disturbances, nausea, decreased appetite, and decreased weight. Since a withdrawal syndrome is indicative of physical dependence, it is reasonable to conclude that generic dronabinol products (both naturally-derived or synthetically produced, and in hard or soft gelatin capsules) in sesame oil, will also produce physical dependence similar to those produced by Marinol®.

Therefore, in this rulemaking, DEA is proposing that 21 CFR 1308.13(g)(1) be modified to include generic equivalents of Marinol® which are (1) naturally-derived or synthetically produced dronabinol; and/or (2) hard or soft gelatin capsules. These products, once approved by FDA, shall meet the criteria for inclusion in schedule III of the CSA.

Comments and Requests for 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 the Administrative Procedure Act 5 U.S.C. 556 and 557. All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested persons and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may request a hearing 21 CFR 1308.42. Please note that DEA may grant a hearing only "for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable" pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Regulatory Certifications

Executive Order 12866

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 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. DEA is hereby proposing to modify the listing of the Marinol® formulation in schedule III so that certain generic drug products are also included in that listing.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $126,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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.

List of Subjects in 21 CFR Part 1308

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

Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Administrator and Deputy Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100 and 0.104, and appendix to subpart R, sec. 12, the Deputy Administrator hereby orders that Title 21 of the Code of Federal Regulations, part 1308, is proposed to be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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.

2. Section 1308.13 is amended by revising paragraph (g) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(g) *Hallucinogenic substances.*

(1)(i) Dronabinol in sesame oil and encapsulated in a gelatin capsule in a drug product approved for marketing by the U.S. Food and Drug Administration (FDA)—7369.

(ii) Any drug product in hard or soft gelatin capsule form containing natural dronabinol (derived from the cannabis plant) or synthetic dronabinol (produced from synthetic materials) in sesame oil, for which an abbreviated new drug application (ANDA) has been approved by the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) which references as its listed drug the drug product referred to in the preceding paragraph (g)(1)(i) of this section—7369.

Note to paragraph (g)(1): 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]

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Dated: October 19, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–27502 Filed 10–29–10; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85, 86, 1036, 1037, 1065, 1066, and 1068

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 523, 534, and 535

[EPA–HQ–OAR–2010–0162; NHTSA–2010–0079; FRL–9219–2]

RIN 2060–AP61; RIN 2127–AK74

Public Hearings for Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles

AGENCIES: Environmental Protection Agency (EPA) and National Highway Traffic Safety Administration (NHTSA).

ACTION: Notice of public hearings.

SUMMARY: EPA and NHTSA are announcing public hearings to be held for the joint proposed rules "Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles," which will be published in the near future in the **Federal Register**. The agencies will also accept comment on NHTSA's Draft Environmental Impact Statement. Two hearings will be held, on November 15 and 18, 2010.

DATES: NHTSA and EPA will jointly hold a public hearing on Monday, November 15, 2010, beginning at 11 a.m. local time, and a second hearing on Thursday, November 18, 2010, beginning at 10 a.m. local time. EPA and NHTSA will make every effort to accommodate all speakers that arrive and register. Each hearing will continue until 5 p.m. or until everyone has had a chance to speak. If you would like to present oral testimony at one of these public hearings, please contact the person identified under **FOR FURTHER INFORMATION CONTACT**, at least ten days before the hearing.

ADDRESSES: The November 15 hearing will be held at the Millennium Knickerbocker Hotel Chicago, 163 East Walton Place (at N. Michigan Ave.), Chicago, Illinois 60611. The November 18, 2010 hearing will be held at the Hyatt Regency Cambridge, 575 Memorial Drive, Cambridge, Massachusetts 02139–4896. The hearings will be held at sites accessible to individuals with disabilities.

FOR FURTHER INFORMATION CONTACT: If you would like to present oral testimony at a public hearing, please contact Julia MacAllister at EPA by the date specified under **DATES**, at: Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4131; fax number: (734) 214–4050; e-mail address: *macallister.julia@epa.gov* (preferred method for registering), or Assessment and Standards Division Hotline; telephone number; (734) 214–4636; e-mail: *asdinfo@epa.gov.* Please provide the following information: Time you wish to speak (morning, afternoon), name, affiliation, address, e-mail address, and telephone and fax numbers, and whether you require accommodations such as a sign language interpreter.

Questions concerning the proposed rules should be addressed to NHTSA: Rebecca Yoon, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366–2992. EPA: Lauren Steele, Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4788; fax number: (734) 214–4816; e-mail address: *steele.lauren@epa.gov,* or Assessment and Standards Division Hotline; telephone number; (734) 214–4636; e-mail: *asdinfo@epa.gov.* You may learn more about the proposal by visiting NHTSA's or EPA's Web pages at *http://www.nhtsa.gov/fuel-economy* or *http://www.epa.gov/otaq/climate/regulations.htm* or by searching the rulemaking dockets (NHTSA–2010–0079; EPA–HQ–OAR–2010–0162) at *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the public hearings is to provide the public an opportunity to present oral comments regarding NHTSA and EPA's proposal for "Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles." These hearings also offer an opportunity for the public to provide oral comments regarding NHTSA's draft Environmental Impact Statement, accompanying the proposed NHTSA fuel efficiency standards. The proposed rules would establish a comprehensive Heavy-Duty National Program that will reduce greenhouse gas emissions and increase fuel efficiency for on-road heavy-duty vehicles. NHTSA's proposed fuel consumption standards and EPA's proposed carbon dioxide (CO_2) emissions standards would be tailored to each of three regulatory categories: (1) Combination Tractors; (2) Heavy-duty Pickup Trucks and Vans; and (3) Vocational Vehicles, as well as gasoline and diesel heavy-duty engines. EPA's proposed hydrofluorocarbon emissions standards would apply to air conditioning systems in tractors, pickup trucks, and vans, and EPA's proposed nitrous oxide (N_2O) and methane (CH_4) emissions standards would apply to all heavy-duty engines, pickup trucks, and vans. The proposal also includes a request for comment on possible alternative CO_2-equivalent approaches for light-duty vehicles in model years 2012–14.

The proposal for which EPA and NHTSA are holding the public hearings will be published in the near future in the **Federal Register** and is available at the Web pages listed above under **FOR FURTHER INFORMATION CONTACT** and also in the rulemaking dockets. NHTSA's draft Environmental Impact Statement is available on the NHTSA Web page and in NHTSA's rulemaking docket, both