

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 610

[Docket No. 2007N-0264]

#### Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Companion Document to Direct Final Rule; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Food and Drug Administration is correcting a proposed rule that appeared in the **Federal Register** of August 16, 2007 (72 FR 45993). That document proposed to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. The proposal published as a companion document to the direct final rule that published in the same issue of the **Federal Register** (August 16, 2007, 72 FR 45883). Both documents published with a typographical error in the codified section. This document corrects the error in the proposed rule. Elsewhere in this issue of the **Federal Register** we are correcting the error in the direct final rule.

**DATES:** Submit written or electronic comments on the proposed rule by October 30, 2007.

**ADDRESSES:** You may submit comments on the proposed rule, identified by Docket No. 2007N-0264, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

#### Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of the proposed rule (72 FR 45993 at 45995).

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** For information regarding this correction: Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

*For information regarding the proposed rule:* Stephen M. Ripley, Center for Biologics Evaluation and Research (HF-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E7-15942, appearing on page 45993, in the **Federal Register** of Thursday, August 16, 2007, the following correction is made:

#### § 610.53 [Corrected]

1. On page 45996, in the amendment to § 610.53 *Dating periods for licensed biological products*, in the table in paragraph (c), "65° C" is corrected to read "– 65° C" everywhere it appears.

Dated: September 17, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-18802 Filed 9-21-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-308P]

#### Technical Amendment to Listing in Schedule III of Approved Drug Products Containing Tetrahydrocannabinols

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** Under the current schedules of controlled substances in the DEA regulations, among the substances listed in schedule III is a synthetic isomer of tetrahydrocannabinols (THC) contained in a specific formulation of a drug product approved by the U.S. Food and Drug Administration (FDA). As currently written, the DEA regulation would not necessarily include drug products approved by the FDA under section 505(j) of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355) (commonly referred to as generic drugs) that cite the drug product currently listed in schedule III as the reference listed drug. DEA is hereby proposing to modify the regulation so that certain generic drug products are also included in the schedule III listing.

**DATES:** Written comments must be postmarked, and electronic comments must be sent, on or before November 23, 2007.

**ADDRESSES:** Please submit comments, identified by "Docket No. DEA-308," by one of the following methods:

1. *Regular mail:* Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL.

2. *Express mail:* DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301.

3. *E-mail comments directly to agency:* [dea.diversion.policy@doj.gov](mailto:dea.diversion.policy@doj.gov).

4. *Federal eRulemaking portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

*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 Drug Enforcement Administration's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the "FOR FURTHER INFORMATION" paragraph.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

##### I. Summary

Under the Controlled Substances Act (CSA), the schedules of controlled substances are published on an updated basis in the DEA regulations.<sup>1</sup> Currently, one of the substances listed in schedule III is the following: "Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product."<sup>2</sup> This describes the drug product marketed under the brand name Marinol. As explained below, it is possible that generic versions of Marinol could be approved by the FDA yet not fit within the same schedule III listing as Marinol. The rule being proposed here would correct this situation so that certain generic versions of Marinol that might be approved by the FDA in the future will be in the same schedule as Marinol.

##### II. Detailed Explanation

###### Background

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).

At present, Marinol is the only drug product containing any form of THC that has been approved for marketing by the FDA.<sup>3</sup> Accordingly, THC, as a general category, is listed in schedule I of the CSA,<sup>4</sup> while dronabinol contained in the Marinol formulation is listed separately in schedule III. Any other formulation containing dronabinol

(or any other isomer of THC) remains a schedule I controlled substance.<sup>5</sup>

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.<sup>6</sup> 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 abbreviated new drug applications (ANDA) 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. Thus, for example, a sponsor of an ANDA referencing Marinol could propose for approval a capsule formulated with an inactive ingredient other than sesame oil. The generic drug,

<sup>1</sup> 21 U.S.C. 812(a), (c) and n. 1.

<sup>2</sup> 21 CFR 1308.13(g)(1).

<sup>3</sup> The FDA approved Marinol in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. In 1992, the FDA expanded Marinol's approved indications to include the treatment of anorexia associated with weight loss in patients with AIDS.

<sup>4</sup> 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 United States" and "a lack of accepted safety for use \* \* \* under medical supervision." 21 U.S.C. 812(b)(1).

<sup>5</sup> 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.

<sup>6</sup> 51 FR 17476 (May 13, 1986). DEA subsequently transferred the FDA-approved Marinol formulation from schedule II to schedule III. 64 FR 35923 (July 2, 1999).

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.<sup>7</sup> 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 in 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. This proposed rule would amend the description in Schedule III to include products referencing Marinol that are either capsules or tablets and that 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.* § 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 HHS; (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 HHS and a recommendation. The statute requires the DEA and HHS 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.

21 U.S.C. 811(c). Although the recommendations of HHS 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. *See id.* § 811(a), (b).

*Gettman v. DEA*, 290 F.3d 430, 432 (DC Cir. 2002).

The FDA plays an important role within HHS in the development of the HHS medical and scientific 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 medical and scientific 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).

#### *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.*<sup>8</sup> 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 are in the same dosage form, 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 tablet and the listed drug is a capsule.

<sup>8</sup> See also Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), Intro. at p. vi. (27th ed.).

<sup>7</sup> 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.

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 potential generic versions.<sup>9</sup> 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.<sup>10</sup> 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. Moreover, because—from a scientific perspective—the eight-factor analysis for such generic products would lead to the same results as with the innovator drug, this proposed rule would eliminate the needless expenditure of agency resources to conduct redundant eight-factor analyses. (HHS and DEA have already conducted the eight-factor analysis for the Marinol formulation.<sup>11</sup>) In a similar vein, this proposed rule will eliminate an unnecessary administrative hurdle that could otherwise stand in the way of allowing generic drugs to reach the American consumer without undue delay.

Finally, for additional clarity, the proposed rule will 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.”

#### Note Regarding This Proposed Scheduling Action

In accordance with the provisions of the Controlled Substances Act (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

<sup>9</sup> 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.

<sup>10</sup> See note 9.

<sup>11</sup> The last eight-factor analysis for Marinol was completed in 1998, as part of the process of transferring it from schedule II to schedule III. 64 FR 35928 (July 2, 1999).

Procedure Act (5 U.S.C. 556 and 557). Interested persons are invited to submit their comments, objections or requests for a hearing with regard to this proposal. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. Requests for a hearing should be made in accordance with 21 CFR 1308.44 and should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

#### Regulatory Certifications

##### *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. Further, this proposed rule will eliminate an unnecessary administrative hurdle that could otherwise stand in the way of allowing generic drugs to reach the American consumer without undue delay.

##### *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, 3(d)(1).

##### *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 \$120,000,000 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 (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 part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Section 1308.13 is proposed to be 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 soft gelatin capsule in a drug product approved for marketing by the U.S. Food and Drug Administration (FDA)—7369

(ii) Any drug product in tablet or capsule form containing natural dronabinol (derived from the cannabis

plant) or synthetic dronabinol (produced from synthetic materials) 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 which references as its listed drug the drug product referred to in the preceding paragraph (g)(1)(i) of this section.—7369

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

(2) [Reserved]

Dated: September 17, 2007.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. E7-18714 Filed 9-21-07; 8:45 am]

BILLING CODE 4410-09-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[EPA-HQ-SFUND-2005-0011; FRL-8471-4]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of intent to delete the Tabernacle Drum Dump Superfund Site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 2 is issuing this notice of intent to delete the Tabernacle Drum Dump Superfund Site (Site), located in Tabernacle Township, Burlington County, New Jersey from the National Priorities List (NPL) and requests public comment on this action. The NPL is Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300, which the EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended. The EPA and the State of New Jersey, through the New Jersey Department of Environmental Protection, have determined that responsible parties have implemented all appropriate response actions required. No further operation and maintenance activities or five-year reviews are required at this site.

**DATES:** Comments concerning this site may be submitted on or before October 24, 2007.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA-HQ-SFUND-2005-0011, by one of the following methods:

- <http://www.regulations.gov>. Follow on-line instructions for submitting comments.

- *E-mail:* [tomchuk.doug@epa.gov](mailto:tomchuk.doug@epa.gov).

- *Fax:* (212) 637-4429.

- *Mail:* Douglas Tomchuk, Remedial Project Manager, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 19th Floor, New York, NY 10007-1866.

- *Hand delivery:* Douglas Tomchuk, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 19th Floor, New York, NY 10007-1866.

Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID no. EPA-HQ-SFUND-2005-0011. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going to <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other

information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at:

EPA Region 2 Superfund Records Center, 290 Broadway, Room 1828, New York, New York 10007-1866, (212) 637-4308, *Hours:* 9 a.m. to 5 p.m., Monday through Friday, excluding holidays, by appointment only.

Information on the Site is also available for viewing at the Site's information repository located at: Tabernacle Municipal Building, 163 Carranza Road, Tabernacle, New Jersey 08088.

#### FOR FURTHER INFORMATION CONTACT:

Douglas Tomchuk, Remedial Project Manager, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 19th Floor, New York, NY 10007-1866, *Telephone:* (212) 637-3956, *Fax:* (212) 637-4429, *E-mail:* [tomchuk.doug@epa.gov](mailto:tomchuk.doug@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Intended Site Deletions

#### I. Introduction

The Environmental Protection Agency (EPA) Region II announces its intent to delete the Tabernacle Drum Dump, located on Carranza Road in Tabernacle Township, Burlington County, New Jersey, from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B of the NCP, 40 CFR part 300, which EPA promulgated pursuant to section 105 of CERCLA, as amended. The EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of those sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substances Superfund Response Trust Fund (Fund). Pursuant to § 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions if conditions at the site warrant such action.

The EPA will accept comments on the proposal to delete this site for thirty (30) days after publication of this notice in the **Federal Register**.

Section II of this notice explains the criteria for deleting sites from the NPL.