submitted on or after February 11, 2009, must include the information listed in this paragraph for any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999. If information is included in the annual report with respect to any authorized generic drug, a copy of that portion of the annual report must be sent to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, 10903 New Hampshire Ave., Bldg. 51, rm. 4183, Silver Spring, MD 20993–0002 and marked ''Authorized Generic Submission'' or, if FDA has required that annual reports be submitted in an electronic format, the information required by this section must also be submitted in the electronic format.

* * * * *

Dated: September 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22829 Filed 9–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–308W]

Technical Amendment to Listing in Schedule III of Approved Drug Products Containing Tetrahydrocannabinols; Withdrawal of Proposed Rule

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

ACTION: Withdrawal of proposed rule.

SUMMARY: DEA is withdrawing a proposed rule that was published in the **Federal Register** on September 24, 2007 (72 FR 54226) and is terminating the rulemaking. The proposed rule would have revised the DEA regulations with respect to the listing in schedule III of 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). Specifically, the proposed rule would have revised the DEA regulation so that it would also include generic drug products approved by the FDA under section 505(j) of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355) that cite the drug product currently listed in schedule III as the reference listed drug. In view of the comments DEA received in response to the proposed rule, DEA has decided—in lieu of finalizing the proposed rule—to proceed with the process set out in 21 U.S.C. 811 for transferring each such generic drug individually to schedule III.

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:

Under the Controlled Substances Act (CSA), the schedules of controlled substances are published on an updated basis in the DEA regulations. 21 U.S.C. 812(a), (c) and n.1. 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 [FDA] approved product.'' 21 CFR 1308.13(g)(1). This describes the drug product marketed under the brand name Marinol. As explained in the Notice of Proposed Rulemaking (NPRM) (72 FR 54226), 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 proposed rule was intended to correct this situation so that certain generic versions of Marinol that might be approved by the FDA in the future would be in the same schedule as Marinol.

During the comment period, DEA received comments from nine entities (firms, organizations, and one individual). Six of the nine commenters expressed support for the proposed rule,[1] two opposed it, and one stated both that it was ''a good idea'' and ''not a good idea.''[2] One of the commenters that opposed the rule asserted that the rule was not in conformity with the CSA. Specifically, this commenter asserted that, to achieve the intended result of the rule (transferring to schedule III any future FDA-approved generic versions of Marinol that do not fit within the current wording of 21 CFR 1308.13(g)(1)), DEA must engage in formal rescheduling action, following the procedures set forth in 21 U.S.C. 811. Under these procedures, DEA requests from the Department of Health and Human Services (HHS) a scientific and medical evaluation and scheduling recommendation, with DEA and HHS being required to consider the eight factors set forth in 21 U.S.C. 811(b).[3] In addition, both of the commenters that objected to the proposed rule asserted that the unique formulation of Marinol (that which meets the current wording of 21 CFR 1308.13(g)(1)) prevents the drug from having the ''high potential for abuse'' commensurate with controlled substances in schedules I and II. Further, these commenters asserted, generic versions of Marinol that might be approved by the FDA in the future cannot be assumed to have the same potential for abuse as Marinol if they were to differ from Marinol in their formulations or routes of administration. Based on these considerations, one of the objecting commenters asked that DEA withdraw the proposed rule or, in the alternative, grant an administrative hearing to address the issues raised in its objections.

In the NPRM (in the preamble to the proposed rule), DEA addressed the foregoing legal and factual issues raised by the objecting commenters. Having considered the comments, DEA continues to believe that the proposed rule is legally permissible within the structure of the CSA, for the reasons set forth in the NPRM. In addition, having obtained the input and concurrence of the FDA during the development of the proposed rule, DEA believes that the proposed rule accurately reflects the relevant legal considerations under the FDCA and further that it is grounded in sound scientific considerations. It should also be noted that two of the commenters that supported the rule agreed with DEA regarding the core legal and factual issues raised by those commenters that objected to the rule. Nonetheless, DEA must consider what would likely be the practical realities of going forward with the proposed rule at this time.

First, if DEA were to grant the objecting commenter's request for a hearing, the administrative proceedings within the agency would likely take at least two years to complete, taking into account the time to conduct the hearing presided over by an administrative law judge (ALJ), the issuance by the ALJ of a recommended decision, and the

[1] Three of the commenters that supported the rule also said, in somewhat different ways, that the proposed rule should go further—for example, by also transferring marijuana and/or its derivatives out of schedule I or by granting a pending application by a person seeking to become registered to manufacture marijuana.

[2] This commenter suggested that all forms of THC should either be in schedule I or schedule III, but that FDA-approved formulations containing THC should not be listed separately from illicit forms of the drug.

[3] For a discussion of the formal rescheduling procedures under the CSA, see *Gettman* v. *DEA,* 290 F.3d at 430, 432 (D.C. Cir. 2002).

issuance by the Deputy Administrator of a final order. Thereafter, if DEA were to finalize the proposed rule, any person aggrieved by the final rule would be permitted to seek review in the United States Court of Appeals. It can never be automatically assumed that the Court of Appeals will uphold a challenge to an agency rule. Thus, it is conceivable that going forward toward finalizing the proposed rule at this time could result in years of litigation followed by no final rule that actually takes effect.

Given these considerations, DEA believes that the most sound approach from this point forward is to withdraw the proposed rule and proceed instead with a continuation of the formal rescheduling procedures set forth in 21 U.S.C. 811 that are already underway for each of the proposed generic versions of Marinol affected by the proposed rule (those for which the sponsor has submitted to FDA an abbreviated new drug application referencing Marinol but which fall outside the current wording of 21 CFR 1308.13(g)(1)). For each such product, where the proposed marketer has petitioned DEA to initiate rulemaking proceedings to transfer the product into schedule III, DEA has already—prior to the publication of the NPRM—forwarded the petition to FDA for a scheduling evaluation in accordance with the procedures set forth in 21 U.S.C. 811(b).

Thus, the net result of the withdrawal of this proposed rule is that FDA and DEA will continue with the ongoing scheduling evaluations and any resultant rescheduling proceedings for each of the individual proposed generic versions of Marinol, rather than attempting to reschedule all of them simultaneously through the issuance of this proposed rule. DEA believes the former approach, as compared to the latter, is most likely to result in such rescheduling becoming effective in the shortest period of time.

Dated: September 18, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–22839 Filed 9–26–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–121698–08]

RIN 1545–B100

Amendments to Section 7216 Regulations—Disclosure or Use of Information by Preparers of Returns; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations that provide rules relating to the disclosure and use of tax return information by tax return preparers.

DATES: The public hearing, originally scheduled for October 6, 2008 at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Funmi Taylor of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 622–3628 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking by cross-reference to temporary regulations and a notice of public hearing that appeared in the **Federal Register** on Wednesday, July 2, 2008 (73 FR 37910) announced that a public hearing was scheduled for October 6, 2008, at 10 a.m. in the NYU Room (room 2615), Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is under the section 7216 of the Internal Revenue Code.

Outlines of topics to be discussed at the hearing were due on September 15, 2008. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of Monday, September 22, 2008, no one has requested to speak. Therefore, the public hearing scheduled for October 6, 2008 is cancelled.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E8–22824 Filed 9–26–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–143716–04]

RIN 1545–BD67

Declaratory Judgments—Gift Tax Determinations; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations under section 7477 of the Internal Revenue Code (Code) regarding petitions filed with the United States Tax Court for declaratory judgments as to the valuation of gifts.

DATES: The public hearing, originally scheduled for October 16, 2008 at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Funmi Taylor of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 622–3628 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the **Federal Register** on Monday, June 9, 2008 (73 FR 32503) announced that a public hearing was scheduled for October 16, 2008, at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is under section 7447 of the Internal Revenue Code.

The public comment period for these regulations expired on September 8, 2008. Outlines of topics to be discussed at the hearing were due on September 16, 2008. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of Monday, September 22, 2008, no one has requested to speak. Therefore, the public hearing scheduled for October 16, 2008, is cancelled.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E8–22825 Filed 9–26–08; 8:45 am]

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