The establishment will not be considered active and the establishment registration and device listing information will not appear on the FDA Web site until the required information is submitted to and processed by FDA.

15. Amend § 807.35 by revising paragraphs (a) and (b) to read as follows:

§ 807.35 Notification of registrant.

(a) FDA will assign each device establishment a permanent registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by e-mail, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.

* * * * *

16. Revise § 807.37 to read as follows:

§ 807.37 Public availability of establishment registration and device listing information.

Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the act and will be posted on the FDA Web site. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health (HFZ–308), Food and Drug Administration, 10903 New Hampshire Ave., Building 66, rm. 3521, Silver spring, MD 20993–0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.

17. The heading of subpart C is revised to read as set forth below:

Subpart C—Procedures for Foreign Device Establishments

18. Amend § 807.40 by revising paragraphs (a) and (c) and by adding paragraph (d) to read as follows:

§ 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

(a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register such establishment and list such devices using the FDA electronic device registration and listing system in conformance with the procedures in this section, § 807.41, and subpart B of this part. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of the Food and Drug Administration for matters relating to the registration of device establishments and the listing of device products.

* * * * *

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter.

(d) The establishment registration and device listing information shall be in the English language.

19. Add § 807.41 to subpart C to read as follows:

§ 807.41 Identification of importers and persons who import or offer for import.

(a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, e-mail address, and registration number, if any has been assigned, of any importer (defined in § 807.3(x)) of the establishment's devices that is known to the foreign establishment. The foreign establishment must also specify which of the establishment's listed products each importer receives from the foreign establishment.

(b) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, e-mail address, and registration number, if any has been assigned, of each person who imports or offers for import the establishment's devices into the United States. The term "person who imports or offers for import," which is defined in § 807.3(y), includes agents, brokers, or other parties used by the foreign establishment to facilitate the import of its device into the United States.

(c) For each individual or organization identified by the foreign establishment under paragraphs (a) and (b) of this section, the foreign establishment must submit to FDA electronically the current FDA premarket submission number (e.g., PMA, 510(k), HDE, NDA) and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

Dated: March 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6662 Filed 3–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–333]

Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV; Announcement of Hearing

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

ACTION: Notice of hearing on proposed rulemaking.

SUMMARY: This is notice that the Drug Enforcement Administration (DEA) will hold a hearing with respect to the proposed placement of carisoprodol in schedule IV of the Controlled Substances Act (21 U.S.C. 801, *et seq.*). The control of carisoprodol was initially proposed in a Notice of Proposed Rulemaking published in the **Federal**

Register on November 17, 2009 [74 FR 59108].

DATES: Interested persons desiring to participate in this hearing must provide written notice of desired participation as set out below, on or before April 26, 2010.

The hearing will commence on May 4, 2010 at 10 a.m. at 600 Army Navy Drive, Arlington, VA 22202.

ADDRESSES: To ensure proper handling of notification, please reference "Docket No. DEA–333" on all correspondence. Written notification sent via regular or express mail should be sent to Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–8188.

SUPPLEMENTARY INFORMATION:

Background

On November 17, 2009, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (74 FR 59108) to place the substance carisoprodol into schedule IV of the Controlled Substances Act (CSA) (21 U.S.C. 801, *et seq.*). The NPRM stated that, if this scheduling action were finalized, carisoprodol would be subject to the regulatory controls and criminal sanctions of schedule IV, as are applicable to the manufacture, distribution, dispensing, importation, and exportation of carisoprodol and products containing carisoprodol.

The NPRM invited interested parties to submit comments, objections, and requests for hearing on or before December 17, 2009. The DEA received 18 comments in response to the NPRM. Seventeen commenters strongly supported the control of carisoprodol. These commenters included health care providers, an organization representing pharmaceutical manufacturers and distributors, State regulatory agencies and State Departments of Health officials, law enforcement entities and one pain management association.

According to these commenters, carisoprodol products are being diverted, abused, misused, and sold on the street and from Internet sites without legitimate prescriptions. Commenters indicated carisoprodol is being abused with other controlled drugs such as opioids. There are incidences of pain patients addicted to carisoprodol.

While 17 comments were supportive of control, one commenter requested a hearing on the issue. This commenter stated that it believes "that the NPRM and the associated documentation do not provide substantial evidence to support the proposed scheduling of carisoprodol." Additionally, the petitioner stated that "the proposal gives inadequate weight to the negative impact on patient care of scheduling carisoprodol." In requesting a hearing, the commenter stated its intention to present factual information concerning the relative potential for abuse of carisoprodol, and expert opinion concerning the significance and reliability of data cited in the NPRM and associated materials.

All comments received in response to the NPRM are part of the administrative record and will be considered by DEA in determining whether to finalize the rule placing carisoprodol into schedule IV.

Hearing Notification

In response to this request, DEA is convening a hearing on the NPRM. Accordingly, notice is hereby given that a hearing in connection with this proposed scheduling action will commence on May 4, 2010, at 10 a.m. at the Drug Enforcement Administration, 600 Army Navy Drive, Arlington, VA 22202 and will continue until all interested persons, as that term is defined in 21 CFR 1300.01(b)(19), desiring to participate, who have given notice of such desire as prescribed below, have been heard. The hearing will be conducted pursuant to the provisions of 5 U.S.C. 556 and 557, and 21 CFR 1308.41–1308.45, and 1316.41–1316.68.

Every interested person desiring to participate in the hearing shall file a written notice of intention to participate, in duplicate, with the Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, on or before April 26, 2010. Each notice of intention to participate must be in the form prescribed in 21 CFR 1316.48. The commenter who requested the hearing is hereby directed to file with the Administrative Law Judge a notice of its continued intention to participate in the hearing and to state with particularity its interest in the proceeding.

Dated: March 21, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–6763 Filed 3–25–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–134235–08]

RIN 1545–BI28

Furnishing Identifying Number of Tax Return Preparer

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 6109 of the Internal Revenue Code (Code) that provide guidance to tax return preparers on furnishing an identifying number on tax returns and claims for refund of tax that they prepare. These proposed regulations provide guidance on the identifying number of a tax return preparer for tax returns and claims for refund filed before and after the proposed effective date. The proposed regulations describe how the IRS will define the identifying number of tax return preparers. Additional provisions of the proposed regulations provide that tax return preparers must apply for and regularly renew their preparer identifying number as the IRS may prescribe in forms, instructions, or other guidance. This document also invites comments from the public regarding these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by April 26, 2010.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–134235–08), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–134235–08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–134235–08).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Stuart Murray at (202) 622–4940 (not a toll-free number); concerning submissions of comments and requests for a hearing, Richard Hurst at *richard.a.hurst@irscounsel.treas.gov.*

SUPPLEMENTARY INFORMATION: