

The reporting requirement is for a proposed rule (62 FR 18937, April 17, 1997) that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule. FDA received 23 notices in 1999, 30 notices in 2000, and 28 notices in 2001. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03-2458 Filed 1-31-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0015]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization Scheduling Recommendation for Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning a recommendation by the World Health Organization (WHO) to impose international manufacturing and distribution restrictions, under international treaties, on a drug substance. The comments received in response to this notice will be considered in preparing the U.S. position on this proposal for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, April 8 to 17, 2003. This notice is issued under the Controlled Substances Act.

DATES: Submit written or electronic comments by March 1, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To ensure expeditious review of written comments, send a copy by facsimile or e-mail to: James R. Hunter (see following address).

FOR FURTHER INFORMATION CONTACT:

James R. Hunter, Controlled Substances Staff (HFD-9) Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2098, FAX: 301-443-9222, e-mail: hunterj@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (the Convention). Section 201(d)(2)(B) of the Controlled Substances Act (the CSA) (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the Convention that CND proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received notification from the Secretary-General of the United Nations (the Secretary-General) regarding a substance to be considered for control under the Convention. This notification reflects the recommendation from the 33d WHO Expert Committee for Drug Dependence (ECDD), which met September 14 to 16, 2002. In the **Federal Register** of April 9, 2002 (67 FR 17074), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a

notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

II. United Nations Notification

The formal United Nations notification that identifies the drug substance and explains the basis for the recommendation is reproduced below.

Notification on amineptine:

Reference: NAR/CL.12/2002 CS18/02 CU 2002/262.

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that the World Health Organization (WHO), pursuant to article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances, 1971, has notified him that it is of the opinion that amineptine should be placed in Schedule II of that Convention.

Article 2, paragraphs 1 and 4, of the Convention read:

1. If a Party or the World Health Organization has information relating to a substance not yet under international control which in its opinion may require the addition of that substance to any of the Schedules of this Convention, it shall notify the Secretary-General and furnish him with the information in support of that notification. The foregoing procedure shall also apply when a Party or the World Health Organization has information justifying the transfer of a substance from one Schedule to another among those Schedules, or the deletion of a substance from the Schedules."

"4. If the World Health Organization finds: (a) That the substance has the capacity to produce (i)(1) a state of dependence, and (2) central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or (ii) similar abuse and similar ill effects as a substance in Schedule I, II, III or IV, and (b) That there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control, the World Health Organization shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy, together with recommendations on control measures, if any, that would be appropriate in the light of its assessment."

In accordance with the provisions of article 2, paragraph 2, of the 1971 Convention, the Secretary-General hereby transmits the text of that notification as an annex to the present note. The notification together with the assessments and recommendations from WHO as well as any data received from governments on that substance, will also be brought to the attention of the Commission