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]

BILLING CODE 4160–01–S

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–5*H*-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

on Narcotic Drugs at its forty-sixth session in April 2003.

Any decision taken by the Commission with respect to that notification, pursuant to article 2, paragraph 5 of the Convention, will be notified to States Parties in due course.

Article 2, paragraph 5, of the Convention reads:

''The Commission, taking into account the communication from the World Health Organization, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources.''

The Secretary-General would appreciate it if the Government would submit data on seizures of amineptine or on the existence of clandestine laboratories manufacturing it, as well as any economic, social, administrative or other factors the Government may consider relevant to the question of the possible scheduling of amineptine by the Commission.

The Secretary-General would also appreciate it if the requested information could be communicated by 30 January 2003 to the Secretary, Commission on Narcotic Drugs, P.O. Box 500, A–1400 Vienna, Austria, fax: +43–1–26060–5885.

20 December 2002

NAR/CL.12/2002

Annex—Note Addressed to the United Nations by the World Health Organization

The World Health Organization presents its compliments to the United Nations and has the honour to submit, in accordance with article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances, 1971, assessments and recommendations of the World Health Organization, as set forth in the annex hereto, concerning the proposed placement of amineptine in Schedule II of the 1971 Convention.

The World Health Organization avails itself of this opportunity to present to the United Nations the assurance of its highest consideration.

AMINEPTINE (INN)

Substance identification

Amineptine (7-[(10,11–dihydro–5*H*-dibenzo[*a,d*]cyclohepten–5–yl)amino]heptanoic acid) is available as either the free base (CAS 57574–09–1) or as the hydrochloride salt (CAS 30272–08–3). There are no chiral carbon atoms; therefore, no stereoisomers or racemates are possible.

Similarity to known substances and effects on the central nervous system

Amineptine is a synthetic, atypical tricyclic antidepressant with central nervous system stimulating effects. It is an indirect dopamine agonist, selectively inhibiting dopamine uptake and inducing dopamine release, with additional stimulation of the adrenergic system. Its antidepressant effects are similar to other tricyclic antidepressant drugs but it has a more rapid action, is better tolerated and has little cardiovascular, analgesic or anorectic effects. It produces a similar spectrum of pharmacological effects to psychomotor stimulants in Schedule II of the 1971 Convention on Psychotropic Substances.

Dependence potential

There have been few animal studies regarding the dependence or abuse potential of amineptine. However, some clinical studies indicated that amineptine has both dependence and abuse potential, particularly in patients with a previous history of substance abuse. Clinical observations of significant abuse and dependence are reported in patients treated with amineptine in France. Its dependence potential appeared to be associated with its psychomotor stimulant effect. Withdrawal has been clinically manifested by anxiety, insomnia, psychomotor agitation or bulimia. Instances of dependence have been reported in Europe and Asia.

Actual abuse and/or evidence of likelihood of abuse

Amineptine abuse has mainly been reported in Europe and Asia. It has been withdrawn from the market in France, where the drug was developed a few decades ago, for reasons of considerable hepatotoxicity and abuse. Despite this measure, medical use in developing countries, as well as abuse still continues. The abuse-related adverse drug reaction reports for amineptine collected by the international drug monitoring programme indicate a larger number of case reports of abuse and dependence than anorectic stimulants currently placed in Schedule IV of the 1971 Convention on Psychotropic Substances, such as amfepramone. Response of governments to the WHO questionnaire also indicated limited diversion and abuse of the drug. Some reported hospital admissions due to adverse consequences of amineptine abuse.

Therapeutic usefulness

The therapeutic usefulness of amineptine is low because of hepatotoxicity, secondary features such as acne eruption and anxiety and the availability of safer antidepressants. Of the 103 countries that responded to the WHO questionnaire, only 17 indicated amineptine use.

III. Discussion

Although WHO has made specific scheduling recommendations for amineptine, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the Psychotropic Convention include: (1) Acceptance of the WHO recommendations; (2) acceptance of the recommendations to control, but control the drug substance in a schedule other than that recommended; or (3) rejection of the recommendations entirely. Amineptine is not approved for marketing in the United States and is not a controlled substance in the United States. Therefore, current controls in the United States on amineptine do not appear to meet the requirements of the recommended Schedule II of the Psychotropic Convention.

IV. Comments

Interested persons may, submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this notice. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2456 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 27, 2003, from 8 a.m. to 6 p.m., and on February 28, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 27, 2003, from 8 a.m. to approximately 3:45 p.m., the committee will discuss efficacy data for the use of minimally manipulated hematopoietic stem cells from placental/umbilical cord blood for hematopoietic reconstitution for particular age groups. From approximately 3:45 p.m. to 5:30 p.m., the committee will receive updates of