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

research programs in the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research (CBER). On February 28, 2003, from 8 a.m. to approximately 4:30 p.m., the committee will discuss safety issues related to the use of retrovirus vectors in gene therapy clinical trials.

Procedure: On February 27, 2003, from 8 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 20, 2003. On February 27, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. On February 28, oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 20, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 27, 2003, from approximately 5:30 p.m. to 6 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of a review of individual research programs in CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito or Rosanna L. Harvey at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2374 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food 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). The meeting will be open to the public.

Name of Committee: Food 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 Monday, February 24, 2003, from 8:30 a.m. to 5 p.m., and Tuesday, February 25, 2003, from 8:30 a.m. to 5 p.m.

Location: Sheraton College Park Hotel, Salons A, B, and C, 4095 Powder Mill Rd., Beltsville, MD 20705, 301–937–4422.

Contact Person: Sylvia M. Smith, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 24 and 25, 2003, the committee will meet to discuss FDA's action plan for addressing the issue of acrylamide in food and to discuss the findings and recommendations from the Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 10, 2003. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on February 24, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person on or before February 10, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sylvia Smith at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2457 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; 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). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

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 March 12, 2003, from 8:30 a.m. to 5 p.m. and March 13, 2003, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy or Carolyn Jones, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: *REEDYK@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the