1984. FDA will consider these comments in determining whether further amendments to, or revisions of, the March 1983 draft guideline are warranted. Comments should be in two copies (except that individuals may submit single copies), identified with the docket number found in brackets in the heading of this document. The working draft guideline and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 11, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-19060 Filed 7-18-84; 8:45 am]

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[Docket No. 83N-0308]

International Drug Scheduling; Convention on Psychotropic Substances; Stimulant and/or Hallucinogenic Drugs

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit additional data or comments concerning abuse potential, actual abuse, and medical usefulness and trafficking of 28 stimulant and/or hallucinogenic drugs. This information will be considered in preparing a further response from the United States to the World Health Organization (WHO) regarding abuse liability, actual abuse, and trafficking of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting information is required by law.

DATE: Comments by July 30, 1984.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: I. David Wolfson, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The United States is a party to the 1971 Convention on Psychotropic Substances. Article 2 of the Convention on Psychotropic Substances provides that if WHO has information about a substance which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations and provide the Secretary-General with information in support of its opinion. The Controlled Substances Act (CSA) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Convention on Psychotropic Substances that WHO has information that may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of the Department of Health and Human Services (DHHS). The Secretary of DHHS must then publish the notice in the Federal Register and provide opportunity for interested persons to submit comments to assist DHHS in preparing scientific and medical evaluations about the drug or substance.

On July 25, 1983, WHO requested the United States to submit data concerning the abuse potential, actual abuse, and medical usefulness of 30 stimulant and/or hallucinogenic drugs. FDA, on behalf of DHHS and the Secretary, published WHO's request in the Federal Register of September 13, 1983 (48 FR 41096) and provided an opportunity for public comment on the request.

The Secretary of DHHS has received the following additional notice from WHO on behalf of the Secretary-General:

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 draw attention to a request from the Director-General of the World Health Organization for additional assistance in obtaining data on the following twenty-eight substances:

Cathine (norpseudoephedrine)
Cathinone
Clobenzorex
Dimethoxyamphetamine
Dimethoxybromoamphetamine (DOB)
Ethylamphetamine
Fenbutrazate
Fencamfamin
Fenetylline
Fenproporex
Furfenorex
Levamfetamine
Levomethamphetamine
Mefenorex
Methoxyamphetamine (PMA)
Methylenedioxyamphetamine (MDA)
Morazone
Para-methoxyamphetamine
Pemoline
Propylhexedrine
Pyrovalerone
Trimethoxyamphetamine (TMA)
4-Bromo-2,5-dimethoxyphenethylamine
2,5-Dimethoxy-4-ethylamphetamine (DOET)
N,N-Dimethylamphetamine
N-Ethyl-3,4-methylenedioxyamphetamine (N-Ethyl-MDA)
5-Methoxy-3,4-methylenedioxyamphetamine (MMDA)
3,4-Methylenedioxymethamphetamine (MDMA)

By note NAR/CL.14/1983 of 25 July 1983 the Secretary-General had already requested information on these substances and the data received in response to that request was analysed and submitted to WHO. On the basis of a review of that data, the Director-General of WHO notified the Secretary-General that WHO was of the opinion that two of the substances (DOB and MDA) should be included in Schedule I of the Convention on Psychotropic Substances. The proposal to schedule the two substances was notified by the Secretary-General to all States Parties to the Convention by notes NAC/CL.6/1984 and NAR/CL.7/1984 of 12 and 13 June, respectively. At its thirty-first session, in February 1985, the Commission on Narcotic Drugs will decide what action, if any, should be taken with respect to that proposal to include DOB and MDA in Schedule I of the Convention [on] Psychotropic Substances. [These two WHO notifications will be the subject of future Federal Register notices.]

WHO has recently carried out a detailed examination of the procedure to be followed in the matter of reviewing substances for possible recommendation for scheduling under the international drug control treaties. New guidelines for the review procedure have been approved by the WHO Executive Board and the Director-General has decided to entrust responsibility for such review to the WHO Expert Committee on Drug Dependence.

The twenty-second Expert Committee on Drug Dependence, to be convened from 22 to 27 April 1985, will accordingly examine the 28 substances listed above to determine if any further proposals should be made concerning their possible control under the provisions of the Convention on Psychotropic Substances. In this connection, it would be appreciated if the Government would submit any additional data, it deems appropriate on any of the 28 substances. It would greatly assist the Secretary-General if such data were submitted on a substance-by-substance basis following the outline contained in the questionnaire attached to the present note as an annex.

In view of the fact that a report must be prepared for WHO on this subject, it would be appreciated if the information could be transmitted to the Secretary-General by 15 August 1984. Replies should be addressed to the attention of the Director of the Division of Narcotic Drugs, Vienna International Centre, P.O. Box 500, A-1400 Vienna, Austria.

UNITED NATIONS DIVISON OF NARCOTIC DRUGS

Vienna International Centre, A-1400 Vienna, Austria

Questionnaire for data collection for use by the World Health Organization and the Commission on Narcotic Drugs of the Economic and Social Council

SUBSTANCE REPORTED ON: ———

1. Availability of the substance (registered, marketed, dispensed, etc).
2. National control measures applied to the substance as compared to measures applied to narcotic drugs or psychotropic substances (e.g. prescription requirements, licensing of manufacture and distribution, control of import and export, etc.).
3. Extent of abuse of the substance.
4. Degree of seriousness of the public health and social problems* associated with abuse of the substance.
5. Number of seizures of the substance in the illicit traffic during the previous three years and the quantities involved.
6. Identification of the substances as of local or foreign manufacture and indication of any commercial markings.
7. Existnce of clandestine laboratories manufacturing the substance.

Therefore, as required by section 201(d)(2)(A) of the Controlled Substances Act (21 U.S.C. 811(d)(2)(A)), FDA on behalf of DHHS invites interested persons to submit additional data or comments regarding the named 28 drugs. Information submitted in response to previous Federal Register notices need not be resumbitted. The current WHO notification deletes two of the drugs referred to in the September 13, 1983 notice: methoxymethylenedioxyamphetamine and para-oxyamphetamine. WHO has not provided a basis for the deletion.

In the September 13, 1983 notice, FDA discussed the then current marketing and domestic control status of each of the 30 drugs in the United States. There have been no changes concerning the status of any of the drugs.

Data and information received in response to this notice will be used to prepare supplemental scientific and medical information on these drugs in addition to that previously provided by the United States to WHO. (A copy of that information is on file in the Dockets Management Branch under this docket.) DHHS will forward that information to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these durgs and could impose certain recordkeeping requirements on them.

Upon receipt of the information, DHHS wil not make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Rather, DHHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in 1985. Any DHHS position regarding international control of these drugs will be preceded by another Federal Register notice soliciting public comment as required by 21 U.S.C. 811(d)(2)(B).

Interested persons may, on or before July 30, 1984, submit to the Dockets Management Branch (address above) written comments regarding this action. This short comment period is necessary to assure that DHHS may, in a timely fashion, provide the requested comments and data. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should provide data and/or information in the format described in the WHO questionnaire for data collection found above. Comments are to be identifed with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 16, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-19191 Filed 7-17-84; 10:56 am]

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*Examples of pubic health and social problems are acute intoxication, accidents, work, absenteeism, mortality, behaviour problems, criminality, etc. For a thorough examination of the question please refer to the WHO publication entitled "Assessment of Public Health and Social Problems associated with the Use of Psychotropic Drugs" (No. 656 in the WHO Technical Report Series) and Chapter 7 of the WHO publication entitled "Guidelines for the Control of Narcotic and Psychotropic Substances"

Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently in pertinent part at 49 FR 15139, April 17, 1984) is amended to reflect the following changes within the National Eye Institute (NEI): (1) Republish without change the functional statements for program-level and above components; and (2) establish the Biometry and Epidemiology Program (HN-W4). These changes will show the correct standard Administrative Codes (SACs) for the Institute and its program, and more effectively align the organization with the activities of the program and provide proper visibility to a nationally prominent research program in epidemiological and biometrical investigations of visual disorders.

Sec. HN-B, Organization and Functions, is amended as follows: Under the heading *National Eye Institute (HN-W) [formerly (8E)],* delete the functional statements for the Institute and its programs in their entirety, and republish those functional statements to read as follows:

National Eye Institute (HN-W). Conducts, fosters, and supports research on the causes, natural history, prevention, diagnosis, and treatment of disorders of the eye and visual system, and in related fields (including rehabilitation) through: (1) Research performed in its own laboratories and through contracts; (2) a program of research grants and individual and institutional research training awards; (3) cooperative and collaboration with voluntary organizations and other institutions engaged in research and training in the special health problems of the blind; and (4) collection and dissemination of information on research and findings in these areas.

Intramural Research Program (HN-W2). (1) Plans and conducts the Institute's laboratory and clinical research program, which encompasses five major disease areas: retinal and choroidal diseases, corneal diseases, cataract, glaucoma, and sensory and motor disorders of vision, to ensure maximum utilization of available resources in the attainment of Institute objectives; (2) evaluates research efforts and establishes program priorities; (3) allocates funds, space, and personnel ceilings and integrates ongoing and new research activities into the program structure; (4) collaborates with other Insitute and NIH programs and maintains an awareness of national research efforts in program areas; and (5) provides advice to the Institute Director and staff on matters of scientific interest.

Extramural and Collaborative Program (HN-W3). (1) Plans and directs a program of grant and contract support for research and research training in five major disease areas: retinal and choroidal diseases, corneal diseases, cataract, glaucoma, and sensory and motor disorders of vision to ensure maximum utilization of available