DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0101]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Amfepramone (diethylpropion); Amineptine; Buprenorphine; *Delta*–9–tetrahydrocannabinol (dronabinol); Tramadol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of five drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion 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 comments is required by the Controlled Substances Act (CSA).

DATES: Submit written or electronic comments by May 9, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–09305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1999, e-mail: hunterj@cder.FDA.gov.

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 a party to the convention or 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 of the United Nations with information in support of its opinion.

The CSA (21 U.S.C. 811 *et seq.*) (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 it has information that may justify adding a drug or other substances 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 Health and Human Services (the Secretary of HHS). The Secretary of HHS must then publish the notice in the Federal Register and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

I. WHO Notification

The Secretary of HHS received the following notices from WHO:

Ref: C.L.4.2002

WHO QUESTIONNAIRE FOR COLLECTION OF INFORMATION FOR REVIEW OF DEPENDENCE–PRODUCING PSYCHOACTIVE SUBSTANCES

The Director-General of the World Health Organization presents her compliments and has the pleasure of informing Member States that the Thirty-third Expert Committee on Drug Dependence (ECDD) will meet from 17 to 20 September 2002 to review the following substances:

1. Amfepramone (International Nonproprietary Name (INN))[1]
2. Amineptine (INN)
3. Buprenorphine (INN)
4. *Delta*–9–tetrahydrocannabinol[2]
5. Tramadol (INN)

One of the essential elements of the established review procedure is for the Secretariat to collect relevant information from Member States to prepare a Critical Review document for submission to the Expert Committee on Drug Dependence. The World Health Organization invites Member States to collaborate, as in the past, in this process by providing pertinent information mentioned in the attached questionnaire concerning the substances listed above.

Further clarification on any of the above items can be obtained from Quality Assurance and Safety: Medicines (QSM), Essential Drugs and Medicines Policy (EDM), WHO, Geneva, to which replies should be sent not later than 17 May 2002.

GENEVA, 7 February 2002

1. AMFEPRAMONE (INN)

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently registered as a medical product? (Yes/No)

Please indicate trade name(s), dosage form(s) with strength(s) and indication(s):

1.2 Is there other legitimate use of the substance? (No/Yes, it is used for _____.)

1.3 How is the substance supplied? (Imported/Manufactured in the country)

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance abused or misused in your country? (Yes/No/No information)

2.2 If yes, is the abuse increasing? (Yes/No/No information)

2.3 Any information on the extent of public health or social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.)?

3. ILLICIT ACTIVITIES INVOLVING THE SUBSTANCE

3.1 Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.)?

4. IMPACT OF TRANSFER TO A HIGHER SCHEDULE

4.1 If amfepramone is transferred to Schedule III of the Convention on Psychotropic Substances, do you think that its availability for medical use will be reduced? (Yes/No/No opinion)

4.2 If yes, would the reduction adversely affect the provision of medical care? (Yes/No/No opinion)

Please elaborate:

2. AMINEPTINE (INN)

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently registered as a medical product? (Yes/No)

Please indicate trade name(s), dosage form(s) with strength(s) and indication(s):

1.2 Is there other legitimate use of the substance? (No/Yes, it is used for _____.)

1.3 How is the substance supplied? (Imported/Manufactured in the country)

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance abused or misused in your country? (Yes/No/No information)

2.2 If yes, any information on the extent of abuse?

2.3 Any information on the extent of public health or social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.)?

3. ILLICIT ACTIVITIES INVOLVING THE SUBSTANCE

3.1 Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.)?

4. IMPACT OF SCHEDULING

4.1 If amineptine is placed under international control, do you think that its availability for medical use will be reduced? (Yes/No/No opinion)

4.2 If yes, would the reduction adversely affect the provision of medical care? (Yes/No/No opinion)

Please elaborate:

3. BUPRENORPHINE (INN)

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently registered as a medical product? (Yes/No)

Please indicate trade name(s), dosage form(s) with strength(s) and indication(s):

1.2 Is there other legitimate use of the substance? (No/Yes, it is used for _____.)

1.3 How is the substance supplied? (Imported/Manufactured in the country)

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance abused or misused in your country? (Yes/No/No information)

[1] If the reply to the questionnaire provides sufficient information for a critical review.

[2] Including dronabinol (INN).

2.2 If yes, is the abuse increasing? (Yes/No/No information)

2.3 Any information on the extent of public health or social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.)?

3. ILLICIT ACTIVITIES INVOLVING THE SUBSTANCE

3.1 Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.)?

4. IMPACT OF TRANSFER TO SCHEDULE I/II OF THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, ON MEDICAL AVAILABILITY

4.1 If buprenorphine is transferred from Schedule III of the Convention on Psychotropic Substances to either Schedule I or II of the Single Convention on Narcotic Drugs, do you think that its availability for medical use will be reduced? (Yes/No/No opinion)

4.2 If yes, would the reduction adversely affect the provision of medical care? (Yes/No/No opinion)

Please elaborate:

4. *DELTA*–9–TETRAHYDROCANNABINOL[3]

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently registered as a medical product? (Yes/No)

Please indicate trade name(s), dosage form(s) with strength(s) and indication(s):

1.2 If the answer to 1.1 is no, is there other legitimate use of the substance? (Yes/No)

If yes, please describe the purpose of use.

1.3 If there is legitimate use of the substance, how is the substance supplied? (Imported/Manufactured in the country)

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance abused or misused in your country? (Yes/No)

2.2 If yes, any information on the extent of abuse?

2.3 Any information on the extent of public health or social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.)?

3. ILLICIT ACTIVITIES INVOLVING THE SUBSTANCE

3.1 Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.)?

5. TRAMADOL (INN)

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently registered as a medical product? (Yes/No)

Please indicate trade name(s), dosage form(s) with strength(s) and indication(s):

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance abused or misused in your country? (Yes/No/No information)

2.2 If yes, any information on the extent of abuse?

2.3 Any information on the extent of public health or social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.)?

3. ILLICIT ACTIVITIES INVOLVING THE SUBSTANCE

3.1 Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.)?

4. IMPACT OF SCHEDULING

4.1 If tramadol is placed under international control, do you think that its availability for medical use will be reduced? (Yes/No/No opinion)

4.2 If yes, would the reduction adversely affect the provision of medical care? (Yes/No/No opinion)

Please elaborate:

[3] Including dronabinol (INN)

II. Background

Amfepramone, also known in the United States as diethylpropion, is classified as an anorexiant with pharmacological effects similar to the amphetamines. It is marketed in the United States for short term (8 to 12 weeks) use, in conjunction with a regimen of weight reduction based on caloric restriction, in patients with obesity and who have not responded to an appropriate weight reducing regimen (diet or exercise) alone. It is controlled domestically in Schedule IV of the CSA and internationally in Schedule IV of the Psychotropic Convention.

Amineptine is classified as a tricyclic antidepressant. It is not marketed in the United States. It has been marketed in other countries for the treatment of major depressive disorders and has also been studied for its potential use in the treatment of amphetamine withdrawal. In 1999, amineptine products were voluntarily removed from the market in France and Portugal due to risks of misuse and addiction. It is not controlled in the United States under the CSA or internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

Buprenorphine is a semisynthetic opium derivative with partial mu-opioid receptor agonist activity. In the United States buprenorphine is currently only available as a parenteral product and is marketed for the relief of moderate to severe pain. Buprenorphine is also marketed for the treatment of pain in several other countries in both sublingual and parenteral dosage forms. A high-dose formulation of buprenorphine is also marketed in other countries for use in the treatment of opiate dependence. It is currently controlled domestically in Schedule V of the CSA as a narcotic and is controlled internationally in Schedule III of the Psychotropic Convention. In the **Federal Register** of March 21, 2002 (67 FR 13114), the Drug Enforcement Administration published a proposed rule to increase the regulatory controls placed on buprenorphine by rescheduling buprenorphine from a Schedule V narcotic to a Schedule III narcotic.

Delta–9–tetrahydrocannabinol (*delta*–9–THC), the active component of marijuana, is currently controlled in Schedule I of the CSA. Synthetic *delta*–9–THC, or dronabinol, is the active component of the drug product Marinol, which is marketed in the United States as an antiemetic in the setting of cancer chemotherapy and for treatment of AIDS wasting syndrome. Dronabinol in sesame oil and encapsulated in an FDA-approved product is controlled in Schedule III of the CSA. Marinol is the only product that meets this definition. Dronabinol (which is the synthetic equivalent of the natural active component of marijuana, *delta*–9–THC) in any other form is controlled in Schedule I of the CSA. The drug substance dronabinol is controlled internationally in Schedule II of the Psychotropic Convention.

Tramadol is a centrally acting synthetic analgesic. At least two complementary mechanisms of action appear applicable: binding of parent and metabolite to mu-opioid receptors and weak inhibition of the reuptake of norepinephrine and serotonin. It is marketed in the United States for the treatment of moderate to moderately severe pain. Cases of abuse and dependence of tramadol have been reported. It is not controlled in the United States under the CSA or controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

III. Opportunity to Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA (21 U.S.C. 811(d)(2)(A)), FDA, on behalf of the Department of Health and Human Services (DHHS), invites interested persons to submit comments regarding the five named drugs. Any comments received will be considered by DHHS when it prepares a scientific and medical evaluation of these drugs. DHHS will forward a scientific and medical evaluation of these drugs to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs and could impose certain recordkeeping requirements on them.

DHHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, DHHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which

are expected to be made in late 2002. Any DHHS position regarding international control of these drugs will be preceded by another Federal Register notice soliciting public comments as required by section 201(d)(2)(B) of the CSA.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the drugs by May 9, 2002. This abbreviated comment period is necessary to allow sufficient time to prepare and submit the domestic information package by the deadline imposed by WHO. Two copies of any comments are to be submitted, except that individuals may submit one copy. 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 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8493 Filed 4–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), in cooperation with the Department of Defense (DoD), is announcing the following public workshop: ''Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity.'' The workshop will discuss possible strategies for the efficacy testing of investigational anthrax vaccines.

Date and Time: The public workshop will be held on April 23, 2002, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jay P. Sanford Auditorium on the campus of the Uniformed Services University of Health Sciences (USUHS), 4301 Jones Bridge Rd., Bethesda, MD 20814.

Contact: Kerry Davis, Science Applications International Corp. (SAIC), 5340 Spectrum Dr., suite N, Frederick, MD 21703, 301–619–7078, FAX 301–698–6188, e-mail: kerry.davis@det.amedd.army.mil.

Registration: Preregistration is required and must be completed by April 12, 2002. Contact Kerry Davis (see ''*Contact*'' for address) for information about registration, including registration fees. Seating is limited.

If you need special accommodations due to a disability, please contact Kerry Davis at least 7 days in advance of the meeting.

Transcripts: You may request public workshop transcripts in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcripts will be available approximately 15 working days after the meeting at the cost of 10 cents per page. The public workshop transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm

SUPPLEMENTARY INFORMATION: CBER, in cooperation with DoD, is holding a public workshop entitled ''Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity.'' The workshop will discuss: (1) Pathogenesis of *Bacillus anthracis*, (2) animal models of anthrax, (3) immunogenicity data available from human clinical trials of anthrax vaccines, and (4) identification of surrogate markers and possible strategies. The workshop's goal is to expedite the development of anthrax vaccines by providing additional information about efficacy testing of these vaccines.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8463 Filed 4–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0037]

Public Informational Meeting on Antimicrobial Resistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: ''Public Informational Meeting on Antimicrobial Resistance.'' The purpose of this public meeting is to provide the general public the opportunity to hear speakers from the agency, industry, and others to provide information on the issue of antimicrobial resistance so the public can fully participate in the public dialogue about the issue. Attendees will be invited to ask questions during the meeting.

Date and Time: The meeting will be held on April 26, 2002, from 9:30 a.m. to 4:30 p.m. Walk-in registration will begin at 9 a.m. You may submit written or electronic comments at any time, but in order for your comments to be included with others in conjunction with this meeting, please submit comments no later than 180 days after the meeting. Please include the Docket No. 02N–0037 on your comments.

Addresses: The meeting will be held at the Capital Hilton Hotel, Congressional Room, 1001 16th St. (16th and K Sts.), Washington, DC, 202–393–1000. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title and the Docket No. 02N–0037 on your comments.

For General Information Contact: Vash Klein, Center for Veterinary Medicine (CVM) (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, e-mail: cvmmeet@cvm.fda.gov.

For Information About Registration Contact: Ben Horsley, The Shipley Group, at 888–270–2157, FAX 888–270–2158.

Registration: Registration is required. There is no registration fee for the meeting. Limited space is available, and early registration is encouraged. Information about the meeting and the registration form are available on the Internet at www.fda.gov/cvm, click on Antimicrobial Resistance, then scroll down to PUBLIC MEETINGS, April 26, 2002 — *Consumer Meeting on Antimicrobial Resistance*. Please mail or fax the registration form to: FDA/CVM Enrollments —The Shipley Group, Inc., 1584 South 500 West, suite 201, Woods Cross, UT 84087; Ben Horsley at 888–270–2157 or 801– 298–7800, FAX 888–270–2158 or 801–298–7820. Additional information about the meeting and the agenda will be available on the Internet (www.fda.gov/cvm) before the meeting.

Oral Presentations: Please submit requests for oral presentations by April 22, 2002, to FDA/CVM, Attn: Consumer Meeting, Docket No. 02N–0037, 7500 Standish Pl., (HFV–12), rm. 3503,