Dated: August 28, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–20579 Filed 9–4–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0448]**

### International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Gamma-hydroxybutyric acid; Ketamine; Dextromethorphan; N-benzylpiperazine; 1-(3-trifluoromethylphenyl)piperazine; 1-(3-chlorophenyl)piperazine; 1-(4-Methoxyphenyl)piperazine; 1-(3,4-methylenedioxybenzyl)piperazine; Gamma-butyrolactone; 1,4-Butanediol

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 10 drug substances. These comments will be considered in preparing the United States' response 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 October 6, 2008.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** James R. Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5146, Silver Spring, MD 20993-0002, 301 796–3156, e-mail: *james.hunter@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The United States is a party to the 1971 Convention on Psychotropic Substances (the Psychotropic Convention). Article 2 of the Psychotropic Convention 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 should notify the Secretary General of the United Nations (the Secretary-General) and provide the Secretary-General 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 Psychotropic Convention that it has information that may justify: (1) Adding a drug or other substances to one of the schedules of the convention, (2) transferring a drug or substance from one schedule to another, or (3) 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 HHS will consider 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.16.2008

**WHO Questionnaire for Collection of Information for Review of Dependence-Producing Psychoactive Substances**

The World Health Organization presents its compliments and has the pleasure of informing Member States and Associate Members that the Thirty-fifth Expert Committee on Drug Dependence will meet from 20 to 23 April 2009 to review the following substances:

1. Gamma-hydroxybutyric acid (GHB)
2. Ketamine INN
3. Dextromethorphan pINN
4. N-benzylpiperazine (BZP)
5. 1-(3-trifluoromethylphenyl)piperazine (TFMPP)
6. 1-(3-chlorophenyl)piperazine (mCPP)
7. 1-(4-Methoxyphenyl)piperazine (MeOPP)
8. 1-(3,4-methylenedioxybenzyl)piperazine (MDBP)
9. Gamma-butyrolactone
10. 1,4-Butanediol

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 Report 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 substances listed above.

Further clarification on any of the above items can be obtained from Quality Assurance and Safety: Medicines, Department of Medicines Policy and Standards, WHO, Geneva, to which replies should be sent not later than 20 September 2008.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 28 May 2008

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If statistical information requested is not readily available, a brief descriptive answer would be appreciated.

Please attach copies of relevant study reports and other background information as appropriate.

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**1. GAMMA-HYDROXYBUTYRIC ACID (GHB)**

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).

1.7 Are there any technical uses for the substance in your country?

If ''yes,'' please specify (Yes/No).

1.8 Is there any other legitimate use of the substance?

If ''yes,'' please specify (Yes/No).

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

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance used in a harmful way in your country? [1] (Yes/No/Unknown)

2.2 If ''yes,'' any information on how this is used (including route of administration)?

2.3 If ''yes,'' any information on the extent of harmful use?

2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?

3. CONTROL OF THE SUBSTANCE

3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)

3.2 If yes, are there illicit activities involving the substance:

a. clandestine manufacture (Yes/No)

b. smuggling (Yes/No)

c. diversion (Yes/No)

d. other (please specify) (Yes/No)

3.3 Total quantity of seizures (kg/liter/number of ampoules).

3.4 Any additional information with regard to questions 3.2 and 3.3.

4. IMPACT OF SCHEDULING

(Gamma-hydroxybutyrate is in Schedule IV of the Convention on Psychotropic Substances of 1971 currently.)

4.1 If gamma-hydroxybutyric acid (GHB) is placed under more strict international control, do you think that its availability for medical use will be affected? (Yes/No)

4.2 If ''yes,'' how do you think that a transfer will impact its medical availability?

**2. KETAMINE INN**

1.LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).

1.7 Are there any technical uses for the substance in your country?

If ''yes,'' please specify (Yes/No).

1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).

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

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)

2.2 If ''yes,'' any information on how this is used (including route of administration)?

2.3 If ''yes,'' any information on the extent of harmful use?

2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?

3. CONTROL OF THE SUBSTANCE

3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)

3.2 If ''yes,'' are there illicit activities involving the substance:

a. clandestine manufacture (Yes/No)

b. smuggling (Yes/No)

c. diversion (Yes/No)

d. other (please specify) (Yes/No)

3.3 Total quantity of seizures (kg/number of tablets/number of ampoules).

3.4 Any additional information with regard to questions 3.2 and 3.3.

4. IMPACT OF SCHEDULING

(Ketamine is not scheduled in one of the drug conventions currently.)

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

4.2 If ''yes,'' how do you think that scheduling will impact its medical availability?

**3. DEXTROMETHORPHAN pINN**

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).

1.7 Are there any technical uses for the substance in your country? If ''yes,'' please specify (Yes/No).

1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).

[1] Harmful use is defined as a pattern of psychoactive drug use that causes damage to health, either mental or physical. Harmful use of drugs by an individual often has adverse effects on the drug user's family, the community, and society in general.

1.9 If there is a legitimate use of the substance, how is the substance supplied? (Manufactured in the country/Imported/Both)
2. ABUSE OF THE SUBSTANCE
2.1 Is the substance used in a harmful way in your country? (Yes/No /Unknown)
2.2 If ''yes,'' any information on how this is used (including route of administration)?
2.3 If ''yes,'' any information on the extent of harmful use?
2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?
3. CONTROL OF THE SUBSTANCE
3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)
3.2 If ''yes,'' are there illicit activities involving the substance:
a. clandestine manufacture (Yes/No)
b. smuggling (Yes/No)
c. diversion (Yes/No)
d. other (please specify) (Yes/No)
3.3 Total quantity of seizures (kg/number of tablets/number of ampoules).
3.4 Any additional information with regard to questions 3.2 and 3.3.
4. IMPACT OF SCHEDULING
(Dextromethorphan is not scheduled in one of the drug conventions currently.)
4.1 If dextromethorphan is placed under international control, do you think that its availability for medical use will be affected? (Yes/No)
4.2 If ''yes,'' how do you think that scheduling will impact its medical availability?

**4. N-BENZYLPIPERAZINE (BZP)**

1. LEGITIMATE USE OF THE SUBSTANCE
1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)
1.2 If ''yes,'' since when has it been on the market?
1.3 Please indicate registered indications alphabetically.
1.4 Please indicate known off-label medical indications for which the substance is also used in your country.
1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).
1.7 Are there any technical uses for the substance in your country?
If ''yes,'' please specify(Yes/No).
1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).
1.9 If there is a legitimate use of the substance, how is the substance supplied? (Manufactured in the country/Imported/Both)
2. ABUSE OF THE SUBSTANCE
2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)
2.2 If ''yes,'' any information on how this is used (including route of administration)?
2.3 If ''yes,'' any information on the extent of harmful use?
2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?
3. CONTROL OF THE SUBSTANCE
3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)
3.2 If ''yes,'' are there illicit activities involving the substance:
a. clandestine manufacture (Yes/No)
b. smuggling (Yes/No)
c. diversion (Yes/No)
d. other (please specify) (Yes/No)
3.3 Total quantity of seizures (kg/number of tablets/number of ampoules).
3.4 Any additional information with regard to questions 3.2 and 3.3.

**5. 1-(3-TRIFLUOROMETHYL PHENYL)PIPERAZINE (TFMPP)**

1. LEGITIMATE USE OF THE SUBSTANCE
1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)
1.2 If ''yes,'' since when has it been on the market?
1.3 Please indicate registered indications alphabetically.
1.4 Please indicate known off-label medical indications for which the substance is also used in your country.
1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).
1.7 Are there any technical uses for the substance in your country? If ''yes,'' please specify(Yes/No).
1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).
1.9 If there is a legitimate use of the substance, how is the substance supplied? (Manufactured in the country/Imported/Both)
2. ABUSE OF THE SUBSTANCE
2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)
2.2 If ''yes,'' any information on how this is used (including route of administration)?
2.3 If ''yes,'' any information on the extent of harmful use?
2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?
3. CONTROL OF THE SUBSTANCE
3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)
3.2 If yes, are there illicit activities involving the substance:
a. clandestine manufacture (Yes/No)
b. smuggling (Yes/No)
c. diversion (Yes/No)
d. other (please specify) (Yes/No)
3.3 Total quantity of seizures (kg/number of tablets/number of ampoules)

3.4 Any additional information with regard to questions 3.2 and 3.3.

**6. 1-(3-CHLOROPHENYL)PIPERAZINE (MCCP)**

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).

1.7 Are there any technical uses for the substance in your country?

If ''yes,'' please specify (Yes/No).

1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify(Yes/No).

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

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)

2.2 If ''yes,'' any information on how this is used (including route of administration)?

2.3 If ''yes,'' any information on the extent of harmful use?

2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?

3. CONTROL OF THE SUBSTANCE

3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)

3.2 If yes, are there illicit activities involving the substance:

a. clandestine manufacture (Yes/No)

b. smuggling (Yes/No)

c. diversion (Yes/No)

d. other (please specify) (Yes/No)

3.3 Total quantity of seizures (kg/number of tablets/number of ampoules).

3.4 Any additional information with regard to questions 3.2 and 3.3.

**7. 1-(4-METHOXYPHENYL)PIPERAZINE (MeOPP)**

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).

1.7 Are there any technical uses for the substance in your country? If ''yes,'' please specify (Yes/No).

1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).

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

2. ABUSE OF THE SUBSTANCE

2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)

2.2 If ''yes,'' any information on how this is used (including route of administration)?

2.3 If ''yes,'' any information on the extent of harmful use?

2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?

3. CONTROL OF THE SUBSTANCE

3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)

3.2 If ''yes,'' are there illicit activities involving the substance:

a. clandestine manufacture (Yes/No)

b. smuggling (Yes/No)

c. diversion (Yes/No)

d. other (please specify) (Yes/No)

3.3 Total quantity of seizures (kg/number of tablets/number of ampoules).

3.4 Any additional information with regard to questions 3.2 and 3.3.

**8. 1-(3,4-METHYLENEDIOXYBENZYL)PIPERAZINE (MDBP)**

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

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| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).
1.7 Are there any technical uses for the substance in your country? If ''yes,'' please specify (Yes/No).
1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).
1.9 If there is a legitimate use of the substance, how is the substance supplied? (Manufactured in the country/Imported/Both)
2. ABUSE OF THE SUBSTANCE
2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)
2.2 If ''yes,'' any information on how this is used (including route of administration)?
2.3 If ''yes,'' any information on the extent of harmful use?
2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?
3. CONTROL OF THE SUBSTANCE
3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)
3.2 If yes, are there illicit activities involving the substance:
a. clandestine manufacture (Yes/No)
b. smuggling (Yes/No)
c. diversion (Yes/No)
d. other (please specify) (Yes/No)
3.3 Total quantity of seizures (kg/number of tablets/number of ampoules).
3.4 Any additional information with regard to questions 3.2 and 3.3.

**9. GAMMA-BUTYROLACTONE**

1. LEGITIMATE USE OF THE SUBSTANCE
1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)
1.2 If ''yes,'' since when has it been on the market?
1.3 Please indicate registered indications alphabetically.
1.4 Please indicate known off-label medical indications for which the substance is also used in your country.
1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).
1.7 Are there any technical uses for the substance in your country? If ''yes,'' please specify. (Yes/No)
1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).
1.9 If there is a legitimate use of the substance, how is the substance supplied? Manufactured in the country/Imported/Both)
2. ABUSE OF THE SUBSTANCE
2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)
2.2 If ''yes,'' any information on how this is used (including route of administration)?
2.3 If ''yes,'' any information on the extent of harmful use?
2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?
3. CONTROL OF THE SUBSTANCE
3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)
3.2 If yes, are there illicit activities involving the substance:
a. clandestine manufacture (Yes/No)
b. smuggling (Yes/No)
c. diversion (Yes/No)
d. other (please specify) (Yes/No)
3.3 Total quantity of seizures (kg/liter).
3.4 Any additional information with regard to questions 3.2 and 3.3.

**10. 1,4-BUTANEDIOL**

1. LEGITIMATE USE OF THE SUBSTANCE
1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)
1.2 If ''yes,'' since when has it been on the market?
1.3 Please indicate registered indications alphabetically.
1.4 Please indicate known off-label medical indications for which the substance is also used in your country.
1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

| Dosage Form | Strength | Remark |
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1.6 Please indicate brand names alphabetically (no dosage forms, strengths, etc.).
1.7 Are there any technical uses for the substance in your country? If ''yes,'' please specify (Yes/No).
1.8 Is there any other legitimate use of the substance? If ''yes,'' please specify (Yes/No).
1.9 If there is a legitimate use of the substance, how is the substance supplied? (Manufactured in the country/Imported/Both)
2. ABUSE OF THE SUBSTANCE
2.1 Is the substance used in a harmful way in your country? (Yes/No/Unknown)
2.2 If ''yes,'' any information on how this is used (including route of administration)?
2.3 If ''yes,'' any information on the extent of harmful use?

2.4 If ''yes,'' any information on the extent of public health or social problems associated with the harmful use of the substance (statistics on overdose deaths, dependence, etc.)?

3. CONTROL OF THE SUBSTANCE

3.1 Is the substance controlled under legislation that is intended to regulate availability of substances of abuse (Controlled Substances Act or similar)? (Yes/No)

3.2 If yes, are there illicit activities involving the substance:

a. clandestine manufacture (Yes/No)

b. smuggling (Yes/No)

c. diversion (Yes/No)

d. other (please specify) (Yes/No)

3.3 Total quantity of seizures (kg/liter).

3.4 Any additional information with regard to questions 3.2 and 3.3.

## II. Background

Gamma-hydroxybutyric acid (GHB) is classified as a central nervous system depressant. In 2002, FDA approved a GHB-containing product, Xyrem, for the treatment of cataplexy associated with narcolepsy. Xyrem was approved under the regulations in 21 CFR 314.520, and the product labeling contained a comprehensive risk management program, which includes restricted distribution of the drug through a central pharmacy. Xyrem is controlled domestically in Schedule III of the CSA, while bulk GHB and all other material containing GHB is controlled in Schedule I. In addition, illicit use of Xyrem is subject to Schedule I penalties of the CSA. GHB is controlled internationally in Schedule IV of the Psychotropic Convention. The WHO Expert Committee on Drug Dependence pre-reviewed GHB at its thirty-fourth meeting and recommended it for critical review at a future meeting.

Ketamine is classified as a rapid-acting general anesthetic agent used for short diagnostic and surgical procedures that do not require skeletal muscle relaxation. It is marketed in the United States as an injectable. Ketamine is controlled domestically in Schedule III of the CSA. It is not controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs. The WHO Expert Committee on Drug Dependence reviewed ketamine at its thirty-fourth meeting, and recommended that the Secretariat produce an updated version of the critical review for ketamine and present it to the next meeting of the WHO Expert Committee on Drug Dependence.

Dextromethorphan is classified as an oral antitussive agent for treating uncomplicated, nonproductive coughs. It is marketed in the United States without a prescription in mixtures such as syrups, lozenges, or in combination with antihistamines. Dextromethorphan is not controlled domestically or controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

N-benzylpiperazine (BZP) is used as an intermediate in chemical synthesis, but has been taken orally as either powder or tablets and by other routes including smoking or snorting. It has no medical use in the United States. BZP is controlled domestically in Schedule I of the CSA. BZP is not controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

1-(3-trifluoromethylphenyl)piperazine (TFMPP) is a piperazine-based serotonin receptor agonist. It has no medical use in the United States. TFMPP is not controlled domestically or controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

1-(3-chlorophenyl)piperazine (mCPP) is a piperazine-based serotonin receptor agonist. It has no medical use in the United States. mCPP is not controlled domestically or controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

1-(4-Methoxyphenyl)piperazine (MeOPP) is a piperazine-based derivative. It has no medical use in the United States. MeOPP is not controlled domestically or controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

1-(3,4-methylenedioxybenzyl)piperazine (MDBP) is a piperazine derivative with no medical use in the United States. It is not controlled domestically or controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

Gamma-butyrolactone (GBL) is used as a solvent and reagent in chemistry. GBL can be used in the synthesis of GHB, and can be converted to the central nervous system depressant drug Gamma-hydroxybutyric acid (GHB) in the body after ingestion. As a precursor in the manufacture of GHB, GBL is controlled domestically as a List I chemical in the United States under the CSA. It is not controlled internationally under the Psychotropic Convention or the Single Convention on Narcotic Drugs.

1,4-Butanediol is used as an industrial solvent for manufacturing and also used for the synthesis of GBL. After ingestion, 1,4-Butanediol can also be converted to the central nervous depressant drug GHB. It has no medical use in the United States. 1,4-Butanediol is not controlled domestically under the CSA in the United States, but is subject to controls in several states under State law.

## 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 HHS, invites interested persons to submit comments regarding the 10 named drugs. HHS will consider any received comments when it prepares a scientific and medical evaluation of these drugs. HHS 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.

HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in early 2010. Any HHS 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the drugs by (see **DATES**). 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 paper copies of any comments are to be submitted, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be

accepted by FDA only through FDMS at http://www.regulations.gov.

Dated: August 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–20564 Filed 9–4–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0038]**

### Peripheral and Central Nervous System Drugs 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*: Peripheral and Central Nervous System Drugs 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 October 23, 2008, from 8 a.m. to 5 p.m.

*Location*: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

*Contact Person*: Diem-Kieu Ngo, 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, FAX: 301–827–6776, e-mail: Diem.Ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda*: The Committee will discuss the clinical development of radionuclide imaging products for the detection of amyloid to assist in the diagnosis of Alzheimer's Disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

*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 on or before October 8, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 30, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 1, 2008.

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 Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: August 27, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8–20577 Filed 9–4–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2007–D–0369] (formerly Docket No. 2007D–0168)**

### Publication of Guidances for Industry Describing Product-Specific Bioequivalence Recommendations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' explaining the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

**DATES:** Submit written or electronic comments on the draft product-specific BE recommendations listed in this notice by December 4, 2008.

**ADDRESSES:** Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft product-specific BE recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the