

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. FDA-2008-N-0448]

International Drug Scheduling; Convention of 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; Reopening of Comment Period

73 FR 60705
10/14/08

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 20, 2008, the comment period for the notice on "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs," published in the **Federal Register** of September 5, 2008 (73 FR 51823), requesting comments on abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 10 drug substances. FDA is taking this action in response to a request for a reopening of the comment period to allow interested persons additional time to review the notice and submit comments.

DATES: Submit written or electronic comments by October 20, 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:

I. Background

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 the World Health Organization (WHO) has information about a substance, which in its opinion may require international control or changes 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 Controlled Substances Act (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 substance 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.

In the **Federal Register** of September 5, 2008 (73 FR 51823), FDA published a notice requesting comments on the 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 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.

Interested persons were originally given until October 6, 2008, to comment on the 10 named drug substances.

II. Request for Comments

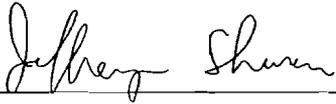
Following publication of the September 5, 2008, notice, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period for comments was insufficient to respond fully to FDA's specific request for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. Therefore, FDA has decided to reopen the comment period on the notice until October 20, 2008, to allow the public more time to review and comment on its contents.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the ten drug substances. Submit a single copy of electronic comments to *<http://www.regulations.gov>* or two paper copies of any mailed comments, 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: 10-7-08
October 7, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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