

ESTIMATED ANNUALIZED BURDEN HOURS

| Forms | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Recruit Letters | 10,754 | 1 | 15/60 | 2,689 |
| Web Survey | 10,754 | 1 | 20/60 | 3,585 |
| Total | | | | 6,274 |

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality (AHRQ), Office for Civil Rights (OCR)

Implementing the Patient Safety and Quality Improvement Act of 2005 Including How to Become a Patient Safety Organization: Interim Guidance Availability

October 14, 2008.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Office for Civil Rights (OCR), HHS.

ACTION: Notice of Availability.

SUMMARY: AHRQ and OCR are announcing the availability of the guidance entitled "Implementing the Patient Safety and Quality Improvement Act of 2005 Including How to Become a Patient Safety Organization." The Interim Guidance document explains how the Department of Health and Human Services (HHS) will begin implementing the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), how an entity can become a Patient Safety Organization (PSO), and how information may be protected as Patient Safety Work Product (PSWP) in the interim period prior to the promulgation of a final regulation. To access the Interim Guidance, visit AHRQ's PSO Web site at <http://www.pso.ahrq.gov>.

DATES: The Interim Guidance is effective immediately with the publication of this notice. The Interim Guidance will remain effective until the effective date of the final regulation, which is expected to be promulgated before the end of 2008.

SUPPLEMENTARY INFORMATION:

I. Background

The Interim Guidance document is intended to inform private, public and

nonprofit health care communities, the legal community and others of HHS's policies and procedures for implementing the Patient Safety Act, prior to the promulgation of a final regulation. This Interim Guidance interprets the Patient Safety Act. The Patient Safety Act (Pub. L. 109-41) amended the Public Health Service Act (42 U.S.C. 299 *et seq.*) by renumbering existing sections and inserting new sections 921 through 926 (42 U.S.C. 299b-21 through 299b-26). The Patient Safety Act authorizes the listing by the Secretary of statutorily defined PSOs. PSOs are to carry out statutorily defined patient safety activities on behalf of providers in order to assist them to improve patient safety. To encourage providers to submit information to PSOs and PSOs to conduct analyses regarding patient safety, the statute establishes privilege and confidentiality protections to protect certain information, including information collected by providers for sharing with PSOs for analysis, analyses performed by the providers and/or the PSOs, and information shared between the PSOs and the health care providers they serve. This information is defined in the statute as PSWP.

II. Significance of the Interim Guidance

The Interim Guidance establishes the process by which the Secretary will list PSOs. Once PSOs are listed by the Secretary, providers can: (1) Voluntarily submit information to PSOs, and (2) seek PSOs' analysis of patient safety events. These activities should lead to improvements in patient safety. The protections established by the Patient Safety Act will permit and encourage numerous providers to submit pertinent data to PSOs so that the PSOs will be able to aggregate and analyze the data from multiple providers, thus enabling the identification of patterns that could suggest underlying or systemic causes of patient risks and hazards that then can be addressed to improve patient safety and quality.

III. Paperwork Reduction Act of 1995

The listing of PSOs under the Interim Guidance involves collecting of information that is subject to review by

the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). These collections of information have been approved under OMB control number 0935-0143.

Dated: October 7, 2008.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. E8-24267 Filed 10-8-08; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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

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: October 7, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-24264 Filed 10-10-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 13 and 14, 2008, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD. The hotel phone number is 301-948-8900.

Contact Person: Kalyani Bhatt, 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:

Kalyani.Bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in Washington, DC area), codes 3014512529 or 3014512535. 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 hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 13 and 14, 2008, the committees will begin with a closed session, from 8 a.m. to 9:15 a.m. Following the closed session, from 9:15 a.m. to 4:30 p.m., the meeting will be open to the public. On November 13, 2008, the committees will discuss new drug application (NDA) 22-324,