limited only by the space available. The meeting room will accommodate approximately 150 people. Interested parties should make hotel reservations directly with the Holiday Inn Select Pittsburgh South (412–833–5300 or 1–800–HOLIDAY) before the cut-off date of June 27, 2005. A special group rate of $94 per night for meeting guests has been negotiated for this meeting. The NIOSH/NPPTL Public Meeting must be referenced to receive this rate. Interested parties should confirm their attendance to this meeting by completing a registration form and forwarding it by e-mail (*npptlevents@cdc.gov*) or fax (304–225–2003) to the NPPTL Event Management Office. A registration form may be obtained from the NIOSH Homepage (*http://www.cdc.gov/niosh*) by selecting conferences and then the event.

An opportunity to make presentations regarding the discussions of concepts for standards and testing processes for PAPR standards and for Closed Circuit, SCBA Breathing Apparatus standards suitable for respiratory protection against CBRN agents, multi-function PAPRs for industrial applications, and guidelines for use of NIOSH-approved CBRN respirators will be given. Requests to make such presentations at the public meeting should be made by e-mail to the NPPTL Event Management Office (*npptlevents@cdc.gov*). All requests to present should include the name, address, telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. Oral presentations should be limited to 15 minutes. After reviewing the requests for presentation, NPPTL Event Management will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Comments on the topics presented in this notice and at the meeting should be mailed to: NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513–533–8285. Comments may also be submitted by e-mail to *niocindocket@cdc.gov*. E-mail attachments should be formatted in Microsoft Word. Comments should be submitted to NIOSH no later than August 19, 2005. Comments regarding the Multi-Function PAPR should reference Docket Number NIOSH–008 in the subject heading. Comments regarding CBRN PAPR should reference Docket Number NIOSH–010 in the subject heading. Comments regarding the CBRN Closed Circuit, SCBA should reference Docket Number NIOSH–039.

Contact for Additional Information: NPPTL Event Management, 3604 Collins Ferry Road, Suite 100, Morgantown, West Virginia 26505–2353, Telephone 304–599–5941 x138, Fax 304-225–2003, E-mail *npptlevents@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 14, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–12057 Filed 6–17–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0186]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit written or electronic comments on the collection of information by August 19, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2 (d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
100.2(d)	1	1	1	10	10

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.2(d) is insignificant because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343–1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Dated: June 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12055 Filed 6–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0549]

Guidance for Industry on Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.'' The guidance was originally published in November 1996. However, because of potentially significant adverse effects seen in healthy subjects who had not previously used clozapine, FDA proposed a revision to the guidance in a draft published in December 2003. FDA did not receive comments on the draft guidance during the comment period. This final version of the 2003 draft guidance includes a change in the recommended patient population as well as other minor changes that are based on current information available to FDA.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lizzie Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This guidance is being issued because of necessary changes to recommendations provided in a previous guidance on the same topic that published in November 1996. In the **Federal Register** of December 30, 2003 (68 FR 75262), FDA published a document that proposed revisions to the 1996 guidance and that provided information to the pharmaceutical industry regarding the design of bioequivalence studies for generic clozapine products.

In the 1996 guidance, FDA recommended that doses of one-half of a 25 milligram clozapine tablet be administered to healthy subjects in bioequivalence studies for generic clozapine products. The guidance also provided an option for conducting studies in the appropriate patient population. However, in the 2003 draft guidance, FDA proposed that such studies not be conducted in healthy subjects because a high number of healthy subjects experienced serious adverse effects such as hypotension, bradycardia, syncope, and asystole during clozapine bioequivalence studies. FDA did not receive comments on the 2003 draft guidance during the comment period.

This final version of the 2003 draft guidance has been further revised to provide recommendations describing the use of an appropriate patient population that is already stable on a dose of clozapine. The use of healthy subjects who had not previously used clozapine is no longer recommended in this final version of the guidance, which will ensure the safety of subjects in bioequivalence studies on clozapine.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clozapine tablets: in vivo and in vitro dissolution testing. It does not create or confer any rights for