furnishing Part A or Part B items or services may bill a patient for items of services denied by Medicare as not reasonable and necessary, under Medicare program standards (Section 1862(a)(1) of title XVIII of the Social Security Act (the Act), or under one of several other statutory bases (Section 1862(a)(9), Section 1814(a)(2)(C), Section 1835(a)(2)(A), Section 1861(dd)(3)(A), Section 1834(j)(1), Section 1834(a)(15), and Section 1834(a)(17)(B) of the Act), if they informed the patient, prior to furnishing the items or services and the patient, after being so informed, agreed to pay for the items or services.; *Frequency:* As-needed; *Affected Public:* Business or other for-profit, not-for-profit institutions, and Individuals or households; *Number of Respondents:* 1,084,932; *Total Annual Responses:* 21,171,480; *Total Annual Hours:* 1,764,290.

4. *Type of Information Request:* New Collection; *Title of Information Collection:* Evaluation of PACE as a Permanent Program and a For-Profit Demonstration; *Form No.:* CMS–10103 (OMB# 0938–NEW); *Use:* The Balanced Budget Act of 1997 (BBA) established PACE as a permanent Medicare program and a state option under Medicaid. It also mandated a for-profit demonstration and a study of the ''quality and cost'' of the permanent program ''under the Medicare and Medicaid programs.'' All PACE Demonstration sites must convert to permanent program sites in 2003. This evaluation will build on the efforts made in the first PACE evaluation (final reports in 2000). Data will be gathered to assess changes in access to care, patient satisfaction, mortality, organizational/operational changes, patient characteristics, outcomes, quality, etc. that have resulted from the BBA legislation. Patient surveys, site surveys, and claims and utilization data gathered at 12 sites will help answer these study questions. Mathematica Policy Research, Inc. is awarded a contract (No. 500–00–0033) to perform this evaluation. A final report is expected in the summer of 2006.; *Frequency:* Other: One-time; *Affected Public:* Individuals or Households, Not-for-profit institutions; *Number of Respondents:* 2,996; *Total Annual Responses:* 2,996; *Total Annual Hours:* 1,723.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 18, 2003.

Melissa Musotto,

Acting, Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–32045 Filed 12–29–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities (PCPID): Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of meeting.

DATES: Thursday, January 29, 2004, from 8:30 a.m. to 5 p.m. and Friday, January 30, 2004, from 8:30 a.m. to 12 p.m. The full Committee meeting of the President's Committee for People with Intellectual Disabilities will be open to the public.

ADDRESSES: The meeting will be held at the Aerospace Center Building, Aerospace Auditorium, 6th Floor East, 370 L'Enfant Promenade, SW., Washington, DC 20447. Individuals with disabilities who need special accommodations in order to attend and participate in the meeting (*i.e.,* interpreting services, assistive listening devices, materials in alternative format) should notify Executive Director, Salley Atwater, at 202–619–0634 no later than January 16, 2004. Effort will be made to meet special requests received after that date, but availability of special needs accommodations to respond to these requests cannot be guaranteed. All meeting sites are barrier free.

Agenda: The Committee plans to discuss critical issues relating to individuals with intellectual disabilities concerning education and transition, family services and support, public awareness, employment, and assistive technology and information.

FOR FURTHER INFORMATION CONTACT: Sally Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, Aerospace Center Building, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone—(202) 619–0634, Fax—(202) 205–9519, E-mail—*satwater@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with intellectual disabilities. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with intellectual disabilities and their families.

Dated: December 16, 2003.

Sally Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. 03–32053 Filed 12–29–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0549]

Draft Guidance for Industry: Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing, Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This draft guidance provides recommendations for sponsors of abbreviated new drug applications (ANDAs) on the design of bioequivalence studies for generic clozapine products. This draft guidance is being issued because an earlier guidance on this topic published in November 1996 needed to be revised to

reflect current agency recommendations. Because of significant potential adverse effects, the agency no longer recommends in vivo bioequivalence testing in healthy subjects.

DATES: Submit written or electronic comments on the draft guidance by March 1, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft 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 draft 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 draft 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 draft guidance for industry entitled ''Clozapine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This draft guidance is intended to provide information to sponsors of ANDAs on the design of bioequivalence studies for generic clozapine products, and revises the recommendations provided in a guidance on the same topic published in November 1996.

In the earlier version of this draft guidance, the agency recommended that doses of clozapine tablets be administered to healthy subjects in bioequivalence studies for generic clozapine products. The earlier guidance also provided the option of conducting studies in the appropriate patient population. Because a high number of healthy subjects in bioeqivalence studies for clozapine products have experienced serious adverse effects such as hypotension, bradycardia, syncope, and asystole during clozapine bioequivalence studies, FDA is no longer recommending such studies be done in healthy subjects.

The draft guidance provides recommendations for two approaches to study the product in the appropriate patient population. One approach is a study design using patients naive to clozapine. This design uses the recommended titration of dosing consistent with the reference product labeling. The alternative study design uses the appropriate patient population already stable on a dose of clozapine. This alternative also appeared in the earlier version of the guidance. The agency believes that the previously recommended design using healthy subjects was adequate to establish bioequivalence of generic clozapine products; however, the safety concerns associated with the use of clozapine in healthy subjects are significant, and the agency is no longer recommending this practice.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on studies to demonstrate the bioequivalence of clozapine tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes or regulations.

II. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Two copies of mailed 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. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, or through the Division of Dockets Management website at *http://www.fda.gov/ohrmr/dockets/default.htm*.

Dated: December 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–31917 Filed 12–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Protection and Advocacy for Individuals with Mental Illness (PAIMI) Final Rule, 42 CFR part 51—(OMB No. 0930–0172—Extension)—These regulations meet the directive under 42 U.S.C. 10826(b) requiring the Secretary to promulgate final regulations to carry out the PAIMI Act. The regulations contain information collection requirements. The Act authorized funds to support activities on behalf of individuals with significant (severe) mental illness (adults) or emotional impairment (children/youth) (42 U.S.C. at 10802(4)). However, only entities designated by the governor of each State and six (6) territories (the American Indian Consortium, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands), and the Mayor of the District of Columbia to protect and advocate the rights of persons with developmental disabilities under Part C of the Developmental Disabilities and Bill of Rights Act (42 U.S.C. 6041 *et seq.*, as amended in 2000) are eligible to receive PAIMI grants (42 U.S.C. at 10802(2)). PAIMI grants are based on a formula prescribed by the Secretary (42 U.S.C. at 10822(a)(1)(A)).

On January 1, each eligible State protection and advocacy (P&A) system is required to prepare and transmit to the Secretary and head of the State Mental Health Agency, in which the system is located, a report describing its activities, accomplishments, and expenditures during the most recently completed fiscal year. Section 10824(a) of the Act requires that the State P&A system's annual reports to the Secretary, shall describe its activities, accomplishments, and expenditures to protect the rights of individuals with mental illness supported with payments from PAIMI allotments, including:

(A) The number of (PAIMI-eligible) individuals with mental illness served;