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