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DATES: Submit written or electronic comments on the draft guidance by March 1, 2004.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ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Clozapine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This draft guidance is intended to provide information to sponsors of ANDAs on the design of bioequivalence studies for generic clozapine products, and revises the recommendations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In the earlier version of this draft guidance, the agency recommended that doses of clozapine tablets be administered to healthy subjects in bioequivalence studies for generic clozapine products.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The draft guidance provides recommendations for two approaches to study the product in the appropriate patient population.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;

(B) A description of the types of activities undertaken;

(C) A description of the types of facilities providing care or treatment to which such activities are undertaken;

(D) A description of the manner in which the activities are initiated;

(E) A description of the accomplishments resulting from such activities;

(F) A description of systems to protect and advocate the rights of individuals with mental illness supported with payments from PAIMI allotments;

(G) A description of activities conducted by States to protect and advocate such rights;

(H) A description of mechanisms established by residential facilities for individuals with mental illness to protect such rights; and,

(I) A description of the coordination among such systems, activities and mechanisms;

(J) Specification of the number of systems that are public and nonprofit systems established with PAIMI allotments; and

(K) Recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of the needs for such activities and services which have not been met by the State P&A systems established under the PAIMI Act. [The PAIMI Rules 42 CFR section 51.32(b) state that P&A systems may place restrictions on case or client acceptance criteria developed as part of its annual PAIMI priorities. However, prospective clients must be informed of any such restrictions at the time they request service].

This summary report must include a separate section, prepared by the PAIMI Advisory Council, that describes the council's activities and its assessment of the operations of the State P&A system (42 U.S.C. 10805(7)). The burden estimate for the annual State P&A system reporting requirements for these regulations is as follows.

42 CFR Citation	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total annual burden
51.8(8)(a)(2) Program Performance Report [1]	57	1	26.0	(1,482)
51.8(8)(a)(8) Advisory Council Report [1]	57	1	10.0	(570)
51.10 Remedial Actions: Corrective Action Plan	7	1	8.0	56
Implementation Status Report	7	3	2.0	42
51.23(c) Reports, materials and fiscal data provided to Advisory Council	57	1	1.0	57
51.25(b)(2) Grievance Procedure	57	1	.5	29
Total	57			184

[1] Burden hours associated with these reports are approved under OMB Control No. 0930–0169.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395–6974.

Dated: December 18, 2003.

Anna Marsh,

Acting Executive Officer, SAMHSA.

[FR Doc. 03–31975 Filed 12–29–03; 8:45 am]

BILLING CODE 4162–20–P

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.

Evaluation of the Buprenorphine Waiver: Longitudinal Patient Survey—New—The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT), is evaluating a program that permits office-based physicians to obtain Waivers from the requirements of the Narcotic Addict Treatment Act of 1974 (21 U.S.C. 823(g)). Under the Drug Addiction Treatment Act of 2000 (21 U.S.C. 823 (g)(2)), the Waiver Program permits qualifying physicians to prescribe and dispense buprenorphine, a schedule III narcotic drug recently approved by the FDA for the treatment of opiate addiction. Furthermore, the Drug Abuse Treatment Act specifies that the Secretary of the Department of Health and Human Services make a determination of whether: (1) Treatments provided under the Waiver Program have been effective forms of maintenance treatment and detoxification treatment in clinical settings; (2) the Waiver Program has significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and, (3) the Waiver Program has adverse consequences for the public health. In addition to the objectives above, the Evaluation of the Buprenorphine Waiver Program will examine other related objectives, including: (1) Describing the impact of the Waiver-based treatment on the existing treatment system; (2) providing information useful to guide and refine the processing/monitoring system being developed and maintained by CSAT/DPT; and (3) providing baseline data to inform future research and policy concerning the medicalization and mainstreaming of addiction treatment.

The evaluation of the Buprenorphine Waiver Program will be accomplished using three survey efforts. The first of these is a mail survey of addiction physicians from the American Society of Addiction Medicine (ASAM) and/or the American Academy of Addiction Psychiatry (AAAP). That survey (approved by OMB under control number 0930–0246) will assess early perceptions of physicians specializing in addiction medicine about whether buprenorphine, as it is prescribed and distributed under the Waiver, is a useful tool in the treatment of substance abuse, and whether they have encountered any negative consequences associated with it.