

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry and reviewers entitled "Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act." The guidance clarifies the processes that will be followed in implementing this section of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This revision includes clarification of the procedures applicable to bulk drug substances for products previously regulated under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), 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 Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For general information regarding this notice: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400.

For issues on bulk drug substance procedures: Gordon R. Johnston, Center for Drug Evaluation and Research (HFD-601), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5845.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a revised guidance for industry and reviewers entitled "Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act." Section 125 of title I of the Modernization Act (Pub. L. 105-115), signed into law by President Clinton on November 21, 1997, repealed section 507 of the act (21 U.S.C. 357). As a result of the repeal of section 507 of the act, which took effect immediately, several of the agency's administrative processes for reviewing and approving antibiotic drug applications had to be changed. This guidance document,

intended to clarify several of the administrative processes that will be followed in implementing section 125 of the Modernization Act, has now been revised to include the procedures applicable to bulk drug substances for products previously marketed under section 507 of the act.

This revised guidance document is a level 1 guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the implementation of the repeal of section 507 of the act. 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 statute, regulations, or both.

Interested persons may, at any time, submit comments on the guidance to the Dockets Management Branch (address above). Two copies of any 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-15769 Filed 6-12-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Disadvantaged Assistance Tracking and Outcome Report (New)

The Health Careers Opportunity Program (HCOP) and the Centers of Excellence (COE) Program (sections 740 and 739 of the Public Health Service (PHS) Act, respectively) provide opportunities for under-represented minorities and disadvantaged individuals to enter and graduate from health professions schools. The Disadvantaged Assistance Tracking and Outcome Report (DATOR) will be used to track program participants through the health professions pathway to a health professions practice outcome. The current inability to track students' education progression in the health professions is a major impediment in assessing the outcome of these programs. There is no identifier used that transcends the various education levels, professional disciplines, and educational institutions.

The DATOR, to be completed annually by HCOP and COE grantees, includes basic data on student participants (name, social security number, gender, race/ethnicity; targeted health professions, their status in the educational pipeline from pre-professional through professional training; financial assistance received through the grants funded under sections 739 and 740 of the PHS Act in the form of stipends, fellowships or per diem; and their employment or practice setting following their entry into the health care work force).

The proposed reporting instrument is not expected to add significantly to the grantees reporting burden. This reporting instrument complements the grantees internal automated reporting mechanisms of using name and social security number in tracking students. Estimates of annualized burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Disadvantaged Assistance Tracking Outcome Report (DATOR)	200	1	10	2,000

Send comments to the HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone number (301) 443-1129. Written comments should be received within 60 days of this Notice.

Dated: June 5, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98-15764 Filed 6-12-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Correction of Meeting Notice

Pursuant to Pub. L. 92-463, notice is hereby given of a correction of a notice of meeting of the SAMHSA Special Emphasis Panel II meeting to be held in July 1998.

Public notice was given in the **Federal Register** on June 9, 1998 (Volume 63, Number 110, page 31517) that the SEP II would be meeting on July 1, 1998, at the Parklawn Building, Room 16C-26. The date of this meeting has subsequently changed to June 29, 1998. The agenda of the meeting and the contact for additional information remain as announced.

Dated: June 9, 1998.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98-15811 Filed 6-12-98; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4351-N-06]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of

Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments are due on or before August 14, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT:

Alan Fox, Economic and Market Analysis Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8222, Washington, DC 20410; telephone (202) 708-0614, Extension 5863; e-mail alan_fox@hud.gov. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Fox.

SUPPLEMENTARY INFORMATION: The Department of Housing and Urban Development will submit the proposed information collection package to OMB for review as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended.)

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Section 8 Random Digit Dialing Fair Market Rent Telephone Survey.

OMB Control Number: 2528-0142.

Description of the need for the information and proposed use: This provides HUD with a fast, inexpensive way to estimate and update Section 8 Fair Market Rents (FMRs) in areas not covered by AHS or CPI surveys, and in areas where FMRs are believed to be incorrect. It also provides estimates of annual rent changes. Section 8(C)(1) of the United States Housing Act of 1937 requires the Secretary to publish Fair Market Rents (FMRs) annually to be effective on October 1 of each year. FMRs are used for the Section 8 Rental Certificate Program (including space rentals by owners of manufactured homes under that program); the Moderate Rehabilitation Single Room Occupancy program; housing assisted under the Loan Management and Property Disposition programs; payment standards for the Rental Voucher program; and any other programs whose regulations specify their use.

Random digit dialing (RDD) telephone surveys have been used for several years to adjust FMRs. These surveys are based on a sampling procedure that uses computers to select statistically random samples of telephone numbers to locate certain types of rental housing units for surveying. HUD contracts with a private company to conduct two types of RDD surveys: (1) Approximately 50 individual FMR areas are surveyed every year to test the accuracy of their FMRs; (2) In addition, 20 RDD surveys are conducted every year to provide updating factors for FMRs not surveyed individually and for Annual Adjustment Factors (AAFs). These surveys are conducted in the nonmetropolitan portions of all 10 HUD regions, and in the 10 metropolitan portions that do not have their own Consumer Price Index (CPI) surveys.

Members of affected public: Individuals or households living in areas surveyed.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The RDD surveys require a great many telephone calls to reach the required number of eligible respondents—those living in 1 or 2 bedroom nonsubsidized rental housing,