

workshop agenda, will be available 3 weeks before the workshop.

DATES: The public workshop will be held on Wednesday, December 18, 1996, from 8:30 a.m. to 5 p.m. Because space is limited, interested parties are encouraged to register as soon as possible, or at least by December 13, 1996. There is no registration fee for the workshop. The administrative docket will remain open until January 31, 1997, to receive written comments, data, information, or views on the draft guidance or the workshop.

ADDRESSES: The public workshop will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD. Persons interested in attending can register by faxing their name and title, organization name, if any, address, telephone and fax numbers to Paul A. David at FAX 301-594-2859.

Three weeks prior to the workshop, a copy of the draft guidance for reviewers, along with a tentative workshop agenda, will be available through CDER's Fax-on-Demand, 301-827-0577 or 800-342-2722, under the index, document no. 0506. Information on the workshop and registration also will be available via the Internet using the World Wide Web (WWW). To connect to the CDER home page, type <http://www.fda.gov/cder> and go to the "What's Happening" section. A transcript of the workshop will be available from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 business days after the workshop at a cost of 10 cents per page.

Written comments on the draft reviewer guidance or on the workshop can be submitted until January 31, 1997, to the Dockets Management Branch (HFA-305), 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of 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. Received comments may be viewed at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Paul A. David, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-120), 5600 Fishers Lane, Rockville, MD 20857, 301-594-5530.

SUPPLEMENTARY INFORMATION: In March 1994, FDA launched a major initiative to develop and implement GRP's. The goal of the GRP's initiative is to identify and implement methods for improving

the quality and efficiency of the clinical reviews of new product applications.

To manage this large initiative, the agency developed a multitask plan to be implemented in stages. Tasks currently under development include: Defining the critical elements of the clinical review; designing a process for feedback, evaluation, and evolution in review practices and procedures; developing a data base on regulatory policy for clinical review; and defining good data handling practices.

The December 18, 1996, workshop is a part of an effort to define the critical elements of the clinical safety review process and develop a guidance for reviewers that describes those elements and sets institutional expectations for each level of review. The guidance being developed is intended for use by agency officers and other clinical reviewers during the review of new drug product applications. The draft guidance will be discussed at the workshop.

The primary goal of the workshop is to provide an opportunity for input from industry, academia, and the public on the principles and methods for the review of clinical safety data in new drug applications. To encourage the exchange of ideas and comments, the day-long workshop has been divided into the following four major sessions: (1) Characterizing the exposed population, establishing the common adverse events profile, establishing the serious adverse events profile, and integrating important safety findings using the review of systems approach. Each session will include a panel discussion and a period at the end for public comment.

The agency hopes to answer the following questions during the workshop: (1) What approaches to safety data review could speed the overall review process? (2) What steps could be taken to standardize the presentation of safety review data? (3) Are there review or review-related issues that are especially troublesome for those submitting safety data? (4) Do some approaches to data presentation make the reviewer's job easier or more difficult?

As it proceeds with the finalization of the guidance for reviewers, the agency will consider carefully all data and information presented at the workshop and submitted in writing on the guidance and workshop

Dated: November 21, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-30509 Filed 11-27-96; 8:45 am]

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Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Uncompensated Services Reporting and Recordkeeping—42 CFR 124, Subpart F (OMB No. 0915-0077)—Extension and Revision

Titles VI and XVI of the PHS Act, commonly known as the Hill-Burton Act, provide for government grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance, facilities are required to provide a "reasonable volume" of services to persons unable to pay. Facilities are also required to provide assurances periodically that the required level of uncompensated care is being provided, and to follow certain notification and recordkeeping procedures. These requirements are referred to as the uncompensated services assurance.

Certain types of facilities can apply for one of four compliance alternatives which reduce the reporting, recordkeeping, and notification requirements. A new compliance alternative has been added to this clearance package.

The regulations contain provision for reporting to the government the amount of free care provided, as well as provisions for following certain notification and recordkeeping procedures. The regulations also define the procedures for applying for certification (and annual recertification) under a compliance alternative. All of these regulations are included in this clearance request. The Uncompensated

Services Assurance Report (USAR) (HRSA form 710) is one of the methods of reporting the amount of free care provided.

There are no changes to the USAR form. The burden estimates have been reduced because many facilities have met their obligation and are no longer

obligated to report. Burden estimates are as follows:

Type of requirement and regulatory citation	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Disclosure Burden (42 CFR):					
Published Notices (124.504(a))	863	1	863	1.0	863
Individual Notices (124.504(c))	863	1	863	50.0	43,150
Determinations of Eligibility (124.507)	863	396	341,748	1.25	427,185
Reporting:					
Uncompensated Services Report—HRSA Form 710 (124.509(a))	374	1	374	14.0	5,236
Application for Compliance Alternatives:					
Public Facilities (124.513)	5	1	5	6.0	30
Small Obligation Facilities (124.514(c))	0				
CHC, MHC, NHSC (124.515(b)(2)(ii) and 124.515(b)(3)(iii)(B))	0				
Charitable Facilities (124.516(c))	2	1	2	6.0	12
Annual Certification for Compliance Alternatives:					
Public Facilities (124.509(b))	355	1	355	0.5	178
Charitable Facilities (124.509(b))	19	1	19	0.5	10
Small Obligation Facilities (124.509(c))	2	1	2	0.5	1
Complaint Information (124.511(a)):					
Individuals	4	1	4	0.25	1
Facilities	4	1	4	0.5	2
Total reporting and notification burden	1,250		344,239		476,668

Recordkeeping requirements	Number of record-keepers	Hours per year	Total hour burden
Non-alternative Facilities (124.510(a))	863	70	60,410
Small Obligation Facilities (124.510(b))	0		
Public Facilities (124.510(b))	0		
Charitable Facilities (124.510(b))	0		

Total burden for this project is estimated to be 537,078 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 22, 1996.

J. Henry Montes,
Associate Administrator for Policy
Coordination.

[FR Doc. 96-30385 Filed 11-27-96; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4124-N-14]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: November 29, 1996.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708-1226; TDD number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: November 22, 1996.

Jacquie M. Lawing,
Deputy Assistant Secretary for Economic
Development.

[FR Doc. 96-30397 Filed 11-27-96; 8:45 am]

BILLING CODE 4210-29-M

[Docket No. FR-4051-N-03]

Mortgagee Review Board Administrative Actions

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In compliance with Section 202(c) of the National Housing Act, notice is hereby given of the cause and description of administrative actions taken by HUD's Mortgagee Review Board against HUD-approved mortgagees.

FOR FURTHER INFORMATION CONTACT: Morris E. Carter, Director, Office of Lender Activities and Program Compliance, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708-1515. (This is not a toll-free number. A Telecommunications Device