

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions." This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of orphan-drug and humanitarian use device (HUD) designation requests and related submissions to the Office of Orphan Products Development (OPD). The submission of these documents in electronic format should improve the agency's efficiency in processing, archiving, and reviewing them.

**DATES:** Submit written or electronic comments on the draft guidance by May 30, 2006. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Electronic Submissions Coordinator, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6A-55, 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:** James D. Bona, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3666.

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions." This draft document provides guidance to industry regarding submissions of designation requests and related submissions to OPD in electronic format. It describes the two methods by which submissions can be made

electronically to OPD. The first is totally electronic through use of FDA's electronic submission gateway pathway and the second is directly to OPD through the use of physical media (e.g., CD-ROMs). Recommendations are described for the formatting and organization of these submissions. A listing of agency contacts for assistance is also provided.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing designation requests and related submissions in electronic format. 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 and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Paperwork Reduction Act of 1995**

This notice contains no new collections of information. The information requested for designation requests and related submissions is already covered by the regulations for orphan-drugs under 21 CFR 316.20 and for HUDs under 21 CFR 814.102. This notice announces the availability of a guidance that provides applicants with an alternative mechanism for submitting designation requests and related submissions to the agency. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/orphan/esub/esub.htm> or at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 24, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-4709 Filed 3-30-06; 8:45 am]

**BILLING CODE 4160-01-S**

**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) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (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, 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: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB No. 0915-0174)—Extension**

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under section 621 of Title VI and section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to

capital through the assumption of the mortgage credit risk by the Federal Government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are

insured under these programs. The information is used to monitor the financial stability of the hospitals to protect the Federal investment in these facilities. The form used for the data

collection is the Hospital Facility Data Abstract. No changes in the form are proposed.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Hospital Facility Data Abstract .....	80	1	1	80

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received with 60 days of this notice.

Dated: March 27, 2006.

**Tina M. Cheatham,**

*Director, Division of Policy Review and Coordination.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Cancellation of Previously Announced Grant Opportunities

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of Cancellation.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces the cancellation of the following grant opportunities that were initially published on Grants.gov Find,

in the HRSA *Preview*, and on the HRSA Web site (<http://www.hrsa.gov/grants/preview/>).

**DATES:** *Effective Date:* March 31, 2006.

**FOR FURTHER INFORMATION CONTACT:** Gail Lipton, Director, Division of Grants Policy, Office of Federal Assistance Management, Telephone (301) 443-6509. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** Based on funds made available through the final fiscal year (FY) 2006 appropriation and a redirection of priorities, HRSA hereby withdraws the following programs and announcements from FY 2006 competition:

HRSA-06-002 .....	Mental Health/Substance Abuse, Oral Health and Comprehensive Pharmacy Services in Section 330-funded Health Centers. <i>Applications Due:</i> January 13, 2006.
HRSA-06-004 .....	New Access Points. <i>Applications Due:</i> February 10, 2006.
HRSA-06-014 .....	Residency Training in Primary Care. <i>Applications Due:</i> February 17, 2006.
HRSA-06-015 .....	Academic Administrative Units in Primary Care. <i>Applications Due:</i> February 17, 2006.
HRSA-06-016 .....	Physician Assistant Training in Primary Care. <i>Applications Due:</i> February 17, 2006.
HRSA-06-017 .....	Residency Training in General and Pediatric Dentistry. <i>Applications Due:</i> February 17, 2006.
HRSA-06-018 .....	Pre-Doctoral Training in Primary Care. <i>Applications Due:</i> February 17, 2006.
HRSA-06-019 .....	Faculty Development in Primary Care. <i>Applications Due:</i> February 17, 2006.
HRSA-06-022 .....	Health Careers Opportunity Program. <i>Applications Due:</i> February 21, 2006.
HRSA-06-024 .....	Center for Health Workforce. <i>Applications Due:</i> August 1, 2006.
HRSA-06-025 .....	Quentin N. Burdick Program For Rural Interdisciplinary Training. <i>Applications Due:</i> January 13, 2006.
HRSA-06-029 .....	Geriatric Education Centers. <i>Applications Due:</i> February 1, 2006.
HRSA-06-031 .....	Allied Health Projects. <i>Applications Due:</i> January 13, 2006.
HRSA-06-036 .....	Pathways to Health Professions. <i>Applications Due:</i> October 3, 2005.
HRSA-06-052 .....	New Access Points in High Poverty Counties. <i>Applications Due:</i> March 15, 2006.
HRSA-06-053 .....	Planning Grants in High Poverty Counties. <i>Applications Due:</i> March 30, 2006.
HRSA-06-055 .....	Health Center Consortia. <i>Applications Due:</i> April 3, 2006.
HRSA-06-056 .....	Healthy Communities Access Program. <i>Applications Due:</i> February 2, 2006.
HRSA-06-057 .....	Health Center Controlled Networks (HCCN). <i>Applications Due:</i> February 17, 2006.
HRSA-06-058 .....	Operational Network Grants (OPN). <i>Applications Due:</i> March 1, 2006.