

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 60 FR 65350, December 19, 1995) is amended to reflect the realignment of the Office of Health and Industry Programs, Center for Devices and Radiological Health (CDRH), Office of Operations, in the Food and Drug Administration (FDA).

The Immediate Office of the Director, Office of Health and Industry Programs will consist of two new staffs; the Regulations Staff and the Staff College. CDRH believes that the establishment of these two new staffs within the Immediate Office of the Director, Office of Health and Industry Programs, will increase visibility to important program areas of the Center.

Under section HF-B, Organization:

1. Insert the following new subparagraphs under paragraph *Office of Health and Industry Programs (HFWG), Center for Devices and Radiological Health (HFW)*, reading as follows:

Program Operations Staff (HFWG-1). Provides all necessary administrative support to the Office.

Provides services to track the status of on-going Office programs as well as all incoming and outgoing congressional and FDA or Center-tracked correspondence.

Provides personnel computer support to Office staff including the evaluation of hardware and software, installation of hardware and software and assistance in resolving hardware and software problems.

Responds to public and government requests for information about medical device and radiation-emitting products. Serves as the Center Consumer Affairs Representative.

Regulations Staff (HFWG-2). Advises the Center Director and appropriate Agency officials on FDA regulation development responsibilities relating to medical devices and radiological health activities. Serves as the Center focal point for liaison on regulations

development activities with the Office of Chief Counsel.

Coordinates the development, review and submission of Federal Register publications for the Center. Prepares position statements for the Center on standards promulgated by other organizations.

Staff College (HFWG-3). Develops necessary training courses for Center employees by providing continuing education credits for selected programs; providing live satellite teleconferences and distance learning telecasts; and coordinating and sponsoring a variety of seminars and lectures.

Performs needs assessments and develops training objectives. Designs courses and course evaluations.

2. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: December 13, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-578 Filed 1-9-97; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, 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, 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

Black Lung Clinic Program Regulatory Requirements (42 CFR 55a) (OMB No. 0915-0081) Extension/No Change—The purpose of the Black Lung Clinics Program (BLCP) is to stimulate and encourage local public and private agencies to improve the health status of coalworkers and to increase coordination with other programs to assist the coalworkers population. The goal of the BLCP is to provide services to minimize the effects of respiratory and pulmonary impairments of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improve the functional status, i.e., "quality of life", of the miner and reduce economic costs associated with morbidity and mortality arising from pulmonary diseases.

This request is for approval of the reporting and recordkeeping requirements in program regulations as follows:

1. 42 CFR 55a.201 and 55a.301—Reporting—Grantees must submit applications for continued grant support. The regulations outline the requirements for grant applications for States (55a.201) and for entities other than States (55a.301).

2. 42 CFR 55a.201 (a) (3)—Recordkeeping—The regulations require that grantees conduct outreach to active and inactive miners, which requires maintenance of a register of persons with pulmonary impairments.

3. 42 CFR 55a.201 (a) (4)—Recordkeeping—The regulations require that individual patient care plans be provided for all patients. This includes development and periodic updating of the patient plans.

Estimates of annualized hour burden are as follows:

Regulatory requirement ¹	Number of record-keepers	Annual hours per record-keeper	Total burden
55a.201(a)(3)—patient registry	14	357	5,000
55a.201(a)(4)—development of patient plans	14	1,214	17,000

Regulatory requirement ¹	Number of record-keepers	Annual hours per record-keeper	Total burden
55a.201(a)(4)—patient plan update	14	1,429	20,000
Total	14	3,000	42,000

¹ The grant application form is cleared under another OMB approval (OMB No. 0937-0189). The burden for completing the application is not reflected in the table above because the burden is reported in the clearance of the application form.

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 7, 1997.
J. Henry Montes,
Director, Office of Policy and Information
Coordination.
[FR Doc. 97-580 Filed 1-9-97; 8:45 am]
BILLING CODE 4160-15-P

National Institutes of Health

Proposed Collection; Comment Request; Special Volunteer and Guest Researcher Assignment

SUMMARY: In compliance with the requirement of Section 3506 (c)(2)(A) of

the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: Special Volunteer and Guest Researcher Assignment. Type of Information Collection Request: Revision of OMB No. 0925-0177; 4/30/97. Need and Use of Information Collection: Form NIH-590 records, names, address, employer, education, and other information on prospective Special Volunteers and Guest Researchers, and is used by the responsible NIH approving official to determine the individual's

qualifications and eligibility for such assignments. The form is the only official record of approved assignment. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Guest Researcher and Special Volunteer candidates. *Estimated Number of Respondents:* 1560. *Estimated Number of Responses Per Respondent:* 1. *Average Burden Hours Per Response:* .08. *Estimated Total Annual Burden Hours Requested:* 125.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Guest Researcher	370	1	.08	29.6
Special Volunteer	1190	1	.08	95.2
Total	1560	1	.08	125

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION:

To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments, contact: Yetta Patterson, Personnel Management Specialist, Office of Human Resource Management, OD, NIH Building 31, Room 1C39, 31 Center Drive MSC 2272, Bethesda, MD 20892-2272.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before March 11, 1997.

Dated: December 26, 1996.
Marvene S. Horwitz,
Acting Director, Office of Human Resource Management.

[FR Doc. 97-640 Filed 1-9-97; 8:45 am]
BILLING CODE 4140-01-M

Proposed Collection; Comment Request; NIH Intramural Research Training Award, Program Application

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the

Office of the Director, National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: NIH Intramural Research Training Award, Program Application. Type of Information Collection Request: Revision of OMB No. 0925-0299; 4/30/97. Need and Use of Information Collection: The proposed information collection activity is for the purpose of collecting data related to the availability of training fellowships under the NIH Intramural Research Training Award Program. This information must be submitted in order to receive due consideration for an award and will be used to determine the eligibility and quality of potential awardess. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Postdoctoral, Predoctoral, Supplemental, Technical,