

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—ESTABLISHMENT FEE ¹

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Payment of annual establishment fee	20	1	20	0.5	10
Request for Small Business Establishment Fee Reduction (Form FDA 3908)	10	1	10	25	250
Total					260

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—REINSPECTION FEE AND DISPUTE RESOLUTION REQUESTS ¹

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Payment of re-inspection fee	5	1	5	0.5	2.5
Reconsideration request	2	1	2	1	2
Appeal request	1	1	1	1	1
Total					5.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Copy of small business designation letter	10	1	10	0.5	5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

Interested persons may submit either electronic comments regarding the guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: March 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at Vol. 79, FR 1882 dated January 10, 2014).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Healthcare Systems Bureau (RR), Office of Pharmacy Affairs (RR7).

Chapter RR—Healthcare Systems Bureau

Section RR-20, Functions

(1) Delete the functional statement for the Office of Pharmacy Affairs (RR7) and replace in its entirety.

Office of Pharmacy Affairs (RR7)

The Office of Pharmacy Affairs promotes access to clinical and cost effective pharmacy services to enable participating entities to stretch scarce federal resources in order to serve more patients, expand their services, or offer additional services. Specifically, the office: (1) Manages the 340B involvement of pharmaceutical manufacturers that participate in the Medicaid program, through Pharmaceutical Pricing Agreements; (2) maintains a publicly accessible database of participating covered entities, sites, and contract pharmacies; (3) publishes guidelines/regulations to assist in the understanding and participation in the 340B Program; (4) maintains a Prime Vendor Program to increase the value of the 340B Program; (5) provides technical assistance to Program stakeholders to support their appropriate and best use of the 340B Program; (6) fosters mutually productive

relationships with federal and private sector partners; (7) provides a national platform for the coordination and development of leading practices for pharmacy services; (8) promotes comprehensive and efficient pharmacy management application and systems use to ensure safe and effective medication use; (9) manages quality improvement activities; and (10) promotes program integrity compliance and improvement activities.

Section RR-30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: March 20, 2014.

Mary K. Wakefield,
Administrator.

[FR Doc. 2014-07177 Filed 3-31-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Special Volunteer and Guest Researcher Assignment, Office of the Director (OD)

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 Intramural Research (OIR), 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.

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 function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the 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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Mr. Larry Chloupek, Management Liaison Director, OIR, Office of the Director, NIH, 2 Center Drive MSC 0235, Bethesda, MD 20892-0235; or call non-toll-free number 301-594-3992; or email your request,

including your address, to larry.chloupek@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Special Volunteer and Guest Researcher Assignment, 0925-0177—EXTENSION—Office of Intramural Research (OIR), National Institutes of Health (NIH).

Need and Use of Information Collection: Form Number NIH-590 is a single form completed by an NIH official for each Guest Researcher or Special Volunteer prior to his/her arrival at the NIH. The information on the form is necessary for the approving official to reach a decision on whether to allow a Guest Researcher to use NIH facilities or whether to accept volunteer services offered by a Special Volunteer. If the original assignment is extended, another form notating the extension is completed to update the file.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours is 166.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Special Volunteers	1,250	1	6/60	125
Guest Researchers	410	1	6/60	41

Dated: March 25, 2014.

Lawrence A. Tabak,
Deputy Director, NIH, Office of the Director.

[FR Doc. 2014-07263 Filed 3-31-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning