

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.30	207	1	207	24	4,968
10.33	4	1	4	10	40
10.35	5	1	5	10	50
10.85	4	1	4	16	64
Total					5,122

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

The burden estimates for this collection of information are based on Agency records.

On December 19, 2013, FDA published a technical amendment (78 FR 76748) announcing that the Agency is modernizing its administrative regulations regarding submission of citizen petitions to explicitly provide for electronic submission. The current regulation does not recognize electronic methods for submitting citizen petitions; thus, this action will enable efficiency and ease in the filing of citizen petitions.

The Agency still allows for non-electronic submissions, however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and straightforward approach. FDA has created a single docket on <http://www.regulations.gov>, the U.S. Government's consolidated docket Web site for Federal Agencies, for the initial electronic submission of all citizen petitions. The FDA Electronic Method for Submission of Citizen Petitions Docket, Docket No. FDA 2013-S-0610, allows the petitioner to create an electronic submission through <http://www.regulations.gov> and provides an alternative to the current system of submission for citizen petitions.

Electronic submissions through <http://www.regulations.gov> will provide the submitter with an immediate record of the time of submission. FDA's Division of Dockets Management (DDM) (<http://www.fda.gov/RegulatoryInformation/Dockets/default.htm>) will continue to inform the submitter of formal filing; however, tracking will be more easily accomplished through electronic submission.

DDM will receive the electronically submitted citizen petition through the Federal Dockets Management System, the Agency component of <http://www.regulations.gov>. Subsequently, DDM will review the electronic submission and when it accepts the citizen petition for filing, DDM will assign a docket number to that petition,

different from the FDA electronic submission docket number. This unique docket number from DDM identifies the docket for that particular citizen petition for all future filings and submissions related only to that citizen petition. Subsequent submissions associated with that citizen petition will refer to the assigned unique docket number. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA, and easier access to FDA to seek input through the citizen petition process.

Dated: March 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014-06132 Filed 3-19-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Functional Glycomics in HIV Vaccine Design.

Date: April 10, 2014 (Subset A).

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3265, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700-B Rockledge Drive, MDS-7616, Bethesda, MD 20892, 301-451-2639, poeky@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Functional Glycomics in HIV Vaccine Design.

Date: April 17, 2014 (Subset B).

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3265, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700-B Rockledge Drive, MDS-7616, Bethesda, MD 20892, 301-451-2639, poeky@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 14, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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