

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 |
|--------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|----------------|
| Food Additive Petitions: | | | | | |
| 571.1(c) Moderate Category | 12 | 1 | 12 | 3,000 | 36,000 |
| 571.1(c) Complex Category | 12 | 1 | 12 | 10,000 | 120,000 |
| 571.6 Amendment of Petition | 2 | 1 | 2 | 1,300 | 2,600 |
| Investigational Food Additive Files: | | | | | |
| 570.17 Moderate Category | 4 | 1 | 4 | 1,500 | 6,000 |
| 570.17 Complex Category | 5 | 1 | 5 | 5,000 | 25,000 |
| Total Hours | | | | | 189,600 |

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

We base our estimate of the total annual responses on submissions received during fiscal years 2016 and 2017. We base our estimate of the hours per response upon our experience with the petition and filing processes.

§ 571.1(c) Moderate Category: For a food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 36,000 hours.

§ 571.1(c) Complex Category: For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 120,000 hours.

§ 571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, two respondents will each submit one such amendment, for a total of 2,600 hours.

§ 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, four respondents will each submit one such file, for a total of 6,000 hours.

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, five respondents will each submit one such file, for a total of 25,000 hours.

The burden for this information collected has not changed since the last OMB approval.

Dated: February 12, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02596 Filed 2-15-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary's Advisory Committee on Infant Mortality (ACIM) has scheduled a public meeting. Information about ACIM and the agenda for this meeting can be found on the ACIM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

DATES: April 8, 2019, from 9:00 a.m. to 5:00 p.m. Eastern Time (ET) and April 9, 2019, from 9:00 a.m. to 3:30 p.m. ET.

ADDRESSES: This meeting will be held remotely via webinar. Instructions on how to access the meeting via webcast will be provided upon registration and on the committee's website at <https://www.hrsa.gov/advisory-committees/Infant-Mortality/index.html>.

FOR FURTHER INFORMATION CONTACT: David S. de la Cruz, Ph.D., MPH, Designated Federal Official (DFO), Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18N-25, Rockville, Maryland 20857; 301-443-0543; or dcruz@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACIM was established under provisions of Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. ACIM is governed by provisions of the Federal

Advisory Committee Act (Pub. L. 92-463). ACIM provides advice and recommendations to the Secretary of HHS regarding HHS programs and activities that focus on reducing infant mortality, improving the health status of infants and pregnant women, and factors affecting the continuum of care with respect to maternal and child health care. ACIM also focuses on: (1) Outcomes before, during, and following pregnancy and childbirth; (2) strategies to coordinate a myriad of federal, state, local, and private programs, and efforts that are designed to deal with the health and social problems impacting infant mortality; and (3) the implementation of the federal *Healthy Start Initiative: Eliminating Disparities in Perinatal Health*.

During the April 2019 meeting, ACIM will discuss updates from HRSA, MCHB, and other federal agencies pertinent to the work of the ACIM; the scope of work and priorities of the ACIM; feedback from ACIM members; and continue the discussion around how health equity is related to infant mortality. Agenda items are subject to change as priorities dictate; please refer to the ACIM website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to to ACIM should be sent to David S. de la Cruz, DFO, using the contact information above at least three business days prior to the meeting. Individuals who plan to attend and need special assistance or another reasonable accommodation should notify David S. de la Cruz at the address and phone number listed above

at least 10 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02623 Filed 2-15-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Security & Strategic Information; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Part A, Chapter AB, Office of the Secretary, which was last amended at 82 FR 205, dated October 25, 2017. This notice changes the name of the Office of Security and Strategic Information to the Office of National Security. This notice does not revise the roles and authorities of the office or the Assistant Deputy Secretary for National Security, who serves as the Secretary's Senior Intelligence Official.

The changes are as follows:

A. Under Chapter AB, Section AB.10 Organization, replace Office of Security and Strategic Information (ABE), with Office of National Security (ABE).

B. Under Chapter AB, Section AB.20, Functions, replace the last paragraph, which begins with "Office of Security and Strategic Information (ABE)," with: Office of National Security (ABE).

The Office of National Security (ONS) is headed by the Assistant Deputy Secretary for National Security, who reports directly to the Deputy Secretary and also serves as the Secretary's Senior Intelligence Official on intelligence and counterintelligence issues. The Assistant Deputy Secretary for National Security has been delegated original classification authority by the Secretary. The Assistant Deputy Secretary for National Security manages the ONS. ONS' vision is for HHS personnel to successfully accomplish missions worldwide in a security-informed manner and with the actionable intelligence needed, at the right time, for operational and policy decisions. ONS' responsibilities include: Integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to the Department and

our national security; and, providing policy guidance on and managing the OS implementation of the Department's security, intelligence and counterintelligence programs. ONS' programs include national security adjudication, classified national security information management, secure compartmented information facilities management, communications security, safeguarding and sharing of classified information, cyber threat intelligence, insider threat, and counterintelligence. In coordination with the Director of National Intelligence, ONS has been designated as a Federal Intelligence Coordinating Office and the Assistant Deputy Secretary for National Security serves as the HHS Federal Senior Intelligence Coordinator. ONS has responsibilities to establish implementing guidance, provide oversight, and manage the Department's policy for the sharing, safeguarding, and coordinated exchange of information related to national or homeland security with other federal departments and agencies, including law enforcement organizations and the Intelligence Community, in compliance with HHS policies and applicable laws, regulations, and Executive Orders.

C. Delegation of Authority. Pending further redelegation, directives or orders made by the Secretary or Deputy Secretary, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Dated: February 12, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019-02663 Filed 2-15-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Eye Institute Special Emphasis Panel; R21 and R01 Data Analysis Applications.

Date: March 19, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 6700 B Rockledge Dr., Ste 3400, Rockville, MD 20892, 301-451-2020, hoshawb@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 12, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-02614 Filed 2-15-19; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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; NIAID Investigator Initiated Program Project Applications (P01).

Date: April 2-5, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.