June 23, 2009, or products in any stage of research or development at any time after June 23, 2009, including experimental products and developmental products intended for introduction into the market for consumer use.

All manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents relating to the deemed tobacco products, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, were submitted by February 8, 2017, or in the case of small-scale deemed tobacco product manufacturers (small-scale manufacturers), by November 8, 2017 (81 FR 28974 at 29008–09). Additionally, FDA extended the compliance deadlines by an additional 6 months for small-scale manufacturers in the areas impacted by recent natural disasters to May 8, 2018. Thereafter, FDA's compliance plan requests deemed manufacturers provide tobacco health document submissions from the specified period, at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600

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

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission for cigars, pipe and waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other tobacco products as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers of deemed tobacco products, or agents thereof, would have health documents to submit. In addition to the existing 4 respondents, the Agency estimates that approximately 6 submissions (2 for cigar manufacturers, 1 for pipe and waterpipe tobacco manufacturers, 1 for other tobacco product manufacturers, 1 for tobacco importers, and 1 for importers of ENDS who are considered manufacturers) will be submitted on an annual basis for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

Based on a review of the information collection of our current OMB approval, we have made no adjustments to our burden estimate.

Dated: August 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18212 Filed 8–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2776]

Evaluating Inclusion and Exclusion Criteria in Clinical Trials; Workshop Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency is announcing the availability of a summary report of a public workshop that was held on April 16, 2018, entitled ''Evaluating Inclusion and Exclusion Criteria in Clinical Trials.'' The FDA Reauthorization Act of 2017 (FDARA) requires that the Agency convene a public workshop to discuss clinical trial eligibility criteria to inform a guidance on this subject and to publish a report summarizing the topics discussed within 90 days of the public workshop. This summary report fulfills FDA's mandate under FDARA.

ADDRESSES: For persons without internet access, copies of the summary report can be requested from the Division of Drug Information, Food and Drug Administration, by mail: 10001 New Hampshire Ave, Silver Spring, MD 20993–0002, or toll free telephone: 855–543–3784.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 51, Rm. 3326, Silver Spring, MD 20993, 301–796–2500, *Dianne.Paraoan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 610 of FDARA requires that FDA convene a public workshop to discuss clinical trial eligibility criteria to inform a guidance on this subject and to publish a report summarizing the topics discussed within 90 days of the public workshop (Pub. L. 115–52). On April 16, 2018, FDA convened the public workshop required by FDARA entitled ''Evaluating Inclusion and Exclusion Criteria in Clinical Trials.'' This notice announces the availability of the report required by FDARA that summarizes the major points explored with stakeholders during the public workshop. The report is intended only as a summary of the workshop

discussions and does not provide guidance or reflect FDA's current thinking on this subject. The workshop report was posted on FDA's website on July 11, 2018.

II. Electronic Access

Persons may obtain the summary report at *https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/ucm598050.htm.*

Dated: August 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18232 Filed 8–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Council on the National Health Service Corps

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

ACTION: Notice of meeting.

SUMMARY: The National Advisory Council on the National Health Service Corps (NACNHSC) has scheduled a public meeting. Information about NACNHSC and the agenda for this meeting can be found on the NACNHSC website at *https://nhsc.hrsa.gov/about/national-advisory-council-nhsc/index.html.*

DATES: September 17, 2018, 9:00 a.m.–5:00 p.m. ET, and September 18, 2018, 9:00 a.m.–2:30 p.m., E.T.

ADDRESSES: This meeting will be held in person and will offer virtual access through teleconference and webinar. The address for the meeting is 5600 Fishers Lane, Room 5W37, Rockville, Maryland 20857.

- *Conference call-in number:* 1–800–238–9007; passcode: 155333.
- Webinar link is *https://hrsa.connectsolutions.com/nacnhsc.*

FOR FURTHER INFORMATION CONTACT: Diane Fabiyi-King, Designated Federal Official (DFO), Division of National Health Service Corps, HRSA, 5600 Fishers Lane, Room 14N110, Rockville, Maryland 20857; 301–443–3609; or *DFabiyi-King@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACNHSC consults, advises, and makes recommendations to the HHS Secretary and the HRSA Administrator with respect to their responsibilities. NACNHSC also reviews and comments on regulations promulgated by the Secretary under Subpart II, Part D of Title III of the Public Health Service Act.

During the September 2018 meetings, NACNHSC will continue its discussion from the May 15, 2018, meeting to develop recommendations on the current NHSC focus areas and finalize policy recommendations to the Secretary and the HRSA Administrator. The current circumstances to strengthen the healthcare workforce and NHSC's role in the expansion and improvement of access to quality opioid and substance use disorder treatment in rural and underserved areas is an important opportunity for NACNHSC to add its voice. For this reason, NACNHSC will develop comprehensive policy recommendations and a framework to articulate a clear vision and mission statement that aligns with the BHW and HRSA strategic plan. An agenda will be posted on the NACNHSC website prior to the meeting. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the NACNHSC should be sent to Monica-Tia Bullock by email at *MBullock@hrsa.gov* at least 3 business days prior to the meeting. Council members are given copies of all written statements submitted from the public. Any further public participation will be solely at the discretion of the Chair, with approval of the DFO. Registration through the designated contact for the public comment session is required. Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Monica-Tia Bullock using the email address listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 10 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–18143 Filed 8–22–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records

AGENCY: Office of Security and Strategic Information (OSSI), Immediate Office of the Secretary (IOS), Department of Health and Human Services (HHS).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended (the Act), the Department of Health and Human Services (HHS) is providing notice of the establishment of a new system of records, System No. 09–90–1701, HHS Insider Threat Program Records. The new system of records will cover records about individuals, retrieved by personal identifier, which are compiled and used by the Department's Office of Security and Strategic Information (OSSI), within the Immediate Office of the Secretary (IOS), to administer the Department's insider threat program. Because the records in this system of records include investigatory material compiled for law enforcement purposes and information classified in the interest of national security, elsewhere in today's **Federal Register** HHS has published a Notice of Proposed Rulemaking (NPRM) to exempt this system of records from certain requirements of the Privacy Act, pursuant to subsections (k)(1) and (k)(2) of the Act. The system of records is more fully described in the **SUPPLEMENTARY INFORMATION** section of this notice and in the System of Records Notice (SORN) published in this notice.

DATES: This system of records is applicable August 23, 2018 with the exception of the routine uses and exemptions. Written comments on the SORN should be submitted by September 24, 2018. If HHS receives no significant adverse comment within the specified comment period, the routine uses will be applicable on September 24, 2018. If any timely significant adverse comment is received, HHS will publish a revised system of records. The exemptions will be applicable following publication of a Final Rule.

ADDRESSES: The public should address written comments on the proposed system of records to *insiderthreat@hhs.gov* or to the HHS Office of Security and Strategic Information (OSSI), 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: General questions about the system of records may be submitted to Michael Schmoyer, Ph.D., Assistant Deputy