into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, *i.e.,* fiscal years 2011 through 2013. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 32 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 247.

In the **Federal Register** of June 10, 2014 (79 FR 33197), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	16	1	16	40	640
Humanitarian device exemption (HDE) application—814.104	7	1	7	320	2,240
HDE amendments and resubmitted HDEs—814.106	14	5	70	50	3,500
HDE supplements—814.108	112	1	112	80	8,960
Notification of withdrawal of an HDE—814.116(e)(3)	8	1	8	1	8
Notification of withdrawal of institutional review board approval—814.124(b)	3	1	3	2	6
Periodic reports—814.126(b)(1)	32	1	32	120	3,840
Total					19,194

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	247	1	247	2	494

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

Dated: November 24, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28183 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1952]

Seventh Annual Sentinel Initiative; Public Workshop; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; amendment of notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a public workshop entitled ''Seventh Annual Sentinel Initiative'' to be held on February 5, 2015. The workshop was announced in the **Federal Register** of October 22, 2014. This amendment reflects the addition of a *Comments* section and updates an incorrect Web site in the *Meeting Materials* section.

FOR FURTHER INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993, 301–796–3714, FAX: 301–847–3529, email: *SentinelInitiative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of October 22, 2014 (79 FR 63130), FDA announced that a public workshop entitled ''Seventh Annual Sentinel Initiative'' will be held on February 5, 2015.

1. On page 63131, in the second column, in the sixth line of the *Meeting Materials* section, the Web site ''*http://www.brookings.edu//health/events*'' is changed to read ''*http://www.brookings.edu/events*''.

2. On page 63131, in the second column, a *Comments* section is added between the *Meeting Materials* section and the *Transcripts* section to read:

''*Comments:* FDA is holding this public workshop to obtain information about a variety of topics on active medical product surveillance. The deadline for submitting comments regarding this public workshop is March 10, 2015.

Regardless of attendance in person or through the Web cast, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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.*''

Dated: November 20, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28196 Filed 11–28–14; 8:45 am]

BILLING CODE 4164–01–P

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 individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council

Date: January 22, 2015.

Open: 8:30 a.m. to 2:00 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Institutes of Health, Terrace Level Conference Rooms, 5635 Fishers Lane, Bethesda, MD 20892.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Terrace Level Conference Rooms, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Anne E Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

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

Dated: November 24, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–28165 Filed 11–28–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2014–0074]

Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement–005 Trade Transparency Analysis and Research (TTAR) System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/Immigration and Customs Enforcement–005 Trade Transparency Analysis and Research (TTAR) System of Records.'' This system of records is being modified to (1) update existing and include new categories of individuals, (2) clarify existing and include new categories of records, (3) reflect a proposed change to the retention period of the system's data, and (4) update the description of the record sources. In addition, the Department is notifying the public of changes triggered by the replacement of the TTAR SORN's associated IT system, the Data Analysis and Research for Trade Transparency System (DARTTS), with FALCON–DARTTS, which replicates the functionality of and serves the same user groups as legacy DARTTS. The TTAR SORN is also being updated to expand coverage to a new IT system called FALCON-Roadrunner. The FALCON–DARTTS and FALCON-Roadrunner Privacy Impact Assessments are posted on the Department privacy Web site (*see www.dhs.gov/privacy*). The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before December 31, 2014. This updated system will be effective December 31, 2014.

ADDRESSES: You may submit comments, identified by docket number DHS–2014–0074 by one of the following methods:

- Federal e-Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: 202–343–4010.
- Mail: Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Lyn Rahilly, Privacy Officer, U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, phone: 202–732–3300, email: *ICEPrivacy@dhs.gov.* For privacy questions, please contact: Karen Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528, phone: 202–343–1717.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Immigration and Customs Enforcement (ICE) proposes to update and reissue a current DHS system of records titled ''DHS/ICE–005 Trade Transparency Analysis and Research (TTAR) System of Records.'' This system allows ICE Homeland Security Investigations (HSI) to collect and maintain records for the purpose of enforcing criminal and civil laws pertaining to customs violations, including trade-based money laundering. With this update, ICE is notifying the public of changes triggered by the replacement of the TTAR SORN's