5. *Healthcare Effectiveness and Outcomes Research (HEOR)*

Date: February 28–March 1, 2018 (Open from 8:30 a.m. to 9:00 a.m. on February 28th and closed for remainder of the meeting).

ADDRESSES: (below specifics where each meeting will be held)

Hilton Rockville & Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427–1554.

SUPPLEMENTARY INFORMATION: These meetings will be closed to the public in accordance with 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committees. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6) 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.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: January 25, 2018.

Gopal Khanna,

Director.

[FR Doc. 2018–01814 Filed 1–30–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2017–0072; Docket Number NIOSH–300]

Final National Occupational Research Agenda for Manufacturing

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final National Occupational Research Agenda for Manufacturing

DATES: The final document was published on January 25, 2018.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/niosh/nora/sectors/manuf/researchagenda.html.*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On August 23, 2017, NIOSH published a request for public review in the **Federal Register** [82 FR 40003] of the draft version of the National Occupational Research Agenda for Manufacturing. All comments received were reviewed and addressed where appropriate.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–01906 Filed 1–30–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60–day–18–18KG; Docket No. CDC–2018–0013]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Information Collection for U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications—CDC is proposing a TB follow-up worksheet to capture domestic TB examination data for persons arriving to the U.S. with overseas TB classifications.

DATES: CDC must receive written comments on or before April 2, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0013 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate 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. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Information Collection for U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications—Existing Information Collection in Use Without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC highly recommends that persons with overseas classification A or B for TB receive U.S. follow-up evaluations to prevent new transmission of TB. This information will assist CDC in fulfilling its regulatory responsibility to prevent the importation and spread of communicable diseases from foreign countries (42 CFR part 71) and interstate control of communicable diseases in humans (42 CFR part 70).

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States. Under its delegated authority in 42 CFR parts 70 and 71, the Division of Global Migration and Quarantine (DGMQ) works to fulfill this responsibility through numerous activities that include monitoring the arrival of persons with Class A and Class B tuberculosis (TB) conditions and coordinating domestic follow-up examinations to prevent new transmission of TB in the United States.

The Secretary of Health and Human Services also has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)) and Section 325 of the Public Health Service Act 42 U.S.C. 252. These regulations are codified in 42 CFR part 34, which establish requirements that determine whether aliens can be admitted into the United States, which includes health examinations when aliens attempt to adjust status to lawful permanent residents.

The TB follow-up worksheet is designed to capture U.S. TB examination data for newly arriving persons to the U.S. with overseas classification A and B for TB. The information collected by the TB follow-up worksheet will provide a method of performing several TB prevention activities, both international and domestic in nature.

The U.S. foreign born population had the highest incidence of TB compared to the U.S. non-foreign born population. CDC strongly recommends incoming persons receive follow-up examinations for TB in the U.S. This data collection will facilitate the methodical collection of TB follow-up outcome data to monitor and track persons with overseas classification A and B for TB and will assist in the national effort to prevent new transmission of TB. To accurately determine rates of TB, recent U.S. arrivals receive domestic follow-up evaluations. U.S. health departments will provide domestic follow-up outcome information to CDC. Without this data, DGMQ will not have a method of tracking and monitoring newly arrived persons with overseas classification A or B for TB. DGMQ will use information reported on the worksheet to ensure that TB programs are effectively tracking new foreign arrivals and coordinating follow-up evaluations with local clinicians. To monitor and evaluate domestic TB program performance, CDC needs to collect data on all elements of TB domestic follow-up up evaluations including CXR, diagnosis, and U.S. treatment outcomes.

The Division of Global Migration and Quarantine (DGMQ) staff along with other federal partners will also use this information to evaluate overseas panel physician performance and overseas prevention activities. To evaluate panel physician performance and overseas TB prevention activities, CDC needs to know the results of domestic chest x-ray (CXR), CXR comparison sputum smear and culture, and TB diagnosis along with domestic reviews of overseas treatment.

There are no costs to respondents except their time to complete the questionnaires. The annualized burden for this data collection is 2,200 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
EDN data entry staff at state and local health departments.	U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications.	550	48	5/60	2,200
Total					2,200

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–01805 Filed 1–30–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–2570; FDA–2015–E–2577]

Determination of Regulatory Review Period for Purposes of Patent Extension; SAPIEN XT TRANSCATHETER HEART VALVE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SAPIEN XT TRANSCATHETER HEART VALVE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 2, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 30, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 2, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 2, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2015–E–2570 and FDA–2015–E–2577 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SAPIEN XT TRANSCATHETER HEART VALVE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff . If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.