

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:**

Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5261, Silver Spring, MD 20993-0002, 240-402-2246, [Christian.Hussong@fda.hhs.gov](mailto:Christian.Hussong@fda.hhs.gov) or ELP Management, [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Additionally, CDRH assures patients and providers have timely and continued access to high-quality, safe, and effective medical devices. Since CDRH has identified Partnering with Patients and Promoting a Culture of Quality and Organizational Excellence as strategic priorities, for the 2018 ELP, our goal is to specifically understand the perspective of our stakeholders and understand implementation of these topics within their institutions. The Center encourages applicants to consider including opportunities to discuss patient perspective and incorporating quality system design and management in their proposals as they contribute to the success of the device development life cycle.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH and other FDA staff with an opportunity to understand the laboratory and manufacturing practices, quality system management, patient perspective/input, and other challenges and how they impact the medical device development life cycle. ELP is a collaborative effort to enhance communication with our stakeholders to facilitate medical device reviews. The Center is committed to understanding current industry practices, innovative technologies, regulatory impacts and needs, and how patient perspective and quality systems management advances the development and evaluation of medical devices, and to monitor the performance of marketed devices.

These formal training visits are not intended for FDA to inspect, assess,

judge, or perform a regulatory function (e.g., compliance inspection), but rather, they are an opportunity to provide CDRH and other FDA staff a better understanding of the products they review, how they are developed, the voice of the patient, challenges related to quality systems development and management in the product life cycle, and how medical devices fit into the larger health care system. CDRH is formally requesting participation from industry, academia, and clinical facilities, medical device incubators and accelerators, health technology assessment groups, and those that have previously participated in the ELP or other FDA site visit programs.

Additional information regarding the CDRH ELP, including the table of areas of interest, submission dates, a sample request, and an example of the site visit agenda, is available on CDRH's Web site at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

**II. CDRH ELP**

**A. Areas of Interest**

In the ELP training program, groups of CDRH and other FDA staff will observe operations in the areas of research, device development, in making coverage decisions and assessments, incorporating patient information and reimbursement, manufacturing, and health care facilities. The areas of interest for visits include various topics identified by managers at CDRH and other areas within FDA. These areas of interest are listed on the ELP Web site and are intended to be updated quarterly.

To submit a proposal addressing one of the Center's training needs, visit the link for the table of areas of interest at: <https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/UCM380676.htm>. Once you have determined an area of interest to address in your ELP proposal, follow the instructions in section III to complete the site visit request template and agenda provided at: <https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf> and at: <https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf>.

Submit all proposals at [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov) within the dates provided at the ELP Web site at: <https://www.fda.gov/scienceresearch/>

[sciencecareeropportunities/ucm380676.htm](https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm).

**B. Site Selection**

CDRH and FDA will be responsible for its own staff travel expenses associated with the site visits. CDRH and FDA will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH and FDA's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding (if applicable). If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history, and must be listed in the proposal along with a Facility Establishment Identifier number, if applicable.

**III. Request To Participate**

Information regarding the CDRH ELP, including a sample request and an example of a site visit agenda, and submission dates is available on CDRH's Web site at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>. Proposals to participate should be submitted to [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov), within the dates provided, at the ELP Web site at <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

Dated: October 13, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-22626 Filed 10-17-17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-5569]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the tracking of medical devices.

**DATES:** Submit either electronic or written comments on the collection of information by December 18, 2017.

**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 December 18, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 18, 2017. 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 No. FDA-2017-N-5569 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking." 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:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the 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. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Medical Devices; Device Tracking—21 CFR Part 821

*OMB Control Number 0910-0442—Extension*

Section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (2) of the Federal Food,

Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(e)(1) and (2)) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a “tracked implant”), or (3) the device is life-sustaining or life-supporting (referred to as a “tracked l/s-l/s device”) and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information.

Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1 through 3 are based on the number of device tracking orders issued in the last 3 years, an average of 12 tracking orders annually. FDA estimates that approximately 22,000 respondents may be subject to tracking reporting requirements.

Under § 821.25(a), device manufacturers subject to FDA tracking orders must adopt a tracking method which can provide certain device, patient, and distributor information to FDA within 3 to 10 working days.

Assuming one occurrence per year, FDA estimates it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under § 821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. Based on the number of audits manufacturers conduct annually, FDA estimates it would receive no more than one notice in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. FDA has not made such a request and is not aware of any manufacturer making a request. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, the Agency estimates a burden of 1 hour to comply.

Under § 821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. FDA’s estimate of the burden for distributor audit responses assumes that manufacturers audit database entries for 5 percent of tracked devices distributed. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, FDA estimates a burden of 1 hour to comply.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d) .....	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e) .....	1	1	1	1	1
Notification of failure to comply—821.25(d) .....	1	1	1	1	1
Multiple distributor data—821.30(c)(2) .....	1	1	1	1	1
Total .....					4

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a) .....	12	1	12	76	912
Record of tracking data—821.25(b) .....	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) <sup>2</sup> .....	12	1	12	63	756
Manufacturer data audit—821.25(c)(3) .....	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d) .....	22,000	1	22,000	1	22,000

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total .....	.....	.....	.....	.....	592,276

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

<sup>2</sup> One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b) .....	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d) .....	1,100	1	1,100	1	1,100
Total .....	.....	.....	.....	.....	23,100

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

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

This document also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget under the PRA (44 U.S.C. 3501–3520). The collections of information found in §§ 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910–0191.

Dated: October 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–22550 Filed 10–17–17; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel; SBIR/STTR Applications in Drug Discovery and Development.

*Date:* November 13, 2017.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, [ruvinser@csr.nih.gov](mailto:ruvinser@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel-Neural Regulation of Cancer.

*Date:* November 13, 2017.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, [zargerma@csr.nih.gov](mailto:zargerma@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Vascular and Hematology.

*Date:* November 13, 2017.

*Time:* 2:00 p.m. to 4:15 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, [pinkusl@csr.nih.gov](mailto:pinkusl@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Parasites-Vectors and Fungi.

*Date:* November 14–15, 2017.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, [elzaataf@csr.nih.gov](mailto:elzaataf@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Biomaterials, Delivery, and Nanotechnology.

*Date:* November 14–15, 2017.

*Time:* 8:00 a.m. to 6:00 p.m.

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

*Place:* Hilton Washington DC/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7760, Bethesda, MD 20892, (301) 404–7419, [rosenzweign@csr.nih.gov](mailto:rosenzweign@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 17–094: Maximizing Investigator’s Research Award (R35).

*Date:* November 14, 2017.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Maqsood A Wani, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114,