

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240-402-3838, email: [marieann.brill@fda.hhs.gov](mailto:marieann.brill@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>. Scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On May 18, 2017, the PAC and the PES will meet to discuss a referral by an Institutional Review Board (IRB) of a clinical investigation that involves children and FDA regulated products. The clinical investigation is entitled “A Double-Blind, Placebo-Controlled, Multi-Center Study with an Open-Label Extension to Evaluate the Efficacy and Safety of SRP-4045 and SRP-4053 in Patients with Duchenne Muscular Dystrophy.” Comments about the upcoming joint meeting should be submitted to Docket No. FDA 2017-N-1780.

After presentation of an overview of the IRB referral process under 21 CFR 50.54, an overview of the protocol and the issues raised by the IRB referral, other relevant presentations about the request to modify the protocol, and a

summary of the public comments received concerning whether the protocol should proceed as modified, the committee will discuss the protocol modification and develop a recommendation regarding whether the protocol should proceed as modified. The committee’s recommendation will then be presented to the Commissioner of Food and Drugs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material will be available at: <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 11, 2017. Oral presentations from the public will be scheduled on May 18, 2017 between approximately 11 a.m. and 12:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 3, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 4, 2017.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Marieann Brill

at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 19, 2017.

**Anna K. Abram,**

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

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2005-N-0464 (Formerly Docket No. 2005N-0403)]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Establishment Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution and Blood Establishment Registration and Product Listing**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that two collections of information: “Establishment Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution” and “Blood Establishment Registration and Product Listing” have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

**SUPPLEMENTARY INFORMATION:** On December 16, 2016, the Agency submitted proposed collections of information entitled “Establishment Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution” and “Blood Establishment Registration and Product Listing” to

OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control numbers 0910–0045 and 0910–0052, respectively. The information collection 0910–0045 expires on December 31, 2018, and the information collection 0910–0052 expires May 31, 2018. Copies of the supporting statements for the information collections are available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 18, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017–08305 Filed 4–24–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–1572]

#### **Cybersecurity of Medical Devices: A Regulatory Science Gap Analysis; Public Workshop; Request for Comments**

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we), in association with National Science Foundation (NSF) and Department of Homeland Security, Science and Technology (DHS S&T) is announcing the following public workshop entitled “Cybersecurity of Medical Devices: A Regulatory Science Gap Analysis.” The objective of the workshop is to facilitate a discussion on the current state of regulatory science in the field of cybersecurity of medical devices, with a focus on patient safety. The purpose of this public workshop is to catalyze collaboration among Health Care and Public Health (HPH) stakeholders to identify regulatory science challenges, discuss innovative strategies to address those challenges, and encourage proactive development of analytical tools, processes, and best practices by the stakeholder community to strengthen medical device cybersecurity.

**DATES:** The public workshop will be held on May 18 and 19, 2017, from 8 a.m. to 6 p.m. Submit either electronic or written comments on the public workshop by June 23, 2017. Late untimely filed comments will not be considered. Electronic comments must be submitted on or before June 23, 2017. The <https://www.regulations.gov/> electronic filing system will accept comments until midnight Eastern Time at the end of June 23, 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. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows:

#### *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 comments will be made public, you are solely responsible for ensuring that your comments do not include any confidential information that you or a third party may not wish to be public, 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–1572 for “Cybersecurity of Medical Devices: A Regulatory Science Gap Analysis.” Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov/> or at the Division of Dockets Management 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 Division of Dockets Management. 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>.

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