The request for information is intended to provide interested persons an opportunity to submit comments relating to FDA’s implementation of the DSCSA. We are particularly interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain. Stakeholders that may be interested in responding to this request for information include: Manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, standards organizations, and other interested persons. FDA is particularly interested in learning about the practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects. This includes, but is not limited to, information about the following:

- Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;
- Technical capabilities each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product; or
- System attributes that are necessary to implement the requirements established under the DSCSA.

Interested persons are requested to provide any other relevant information that may assist with FDA’s development of a pilot project under the DSCSA.

II. Purpose of the Request for Information

The request for information is intended to provide interested persons an opportunity to submit comments relating to FDA’s implementation of the DSCSA. We are particularly interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain. Stakeholders that may be interested in responding to this request for information include: Manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, standards organizations, and other interested persons. FDA is particularly interested in learning about the practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects. This includes, but is not limited to, information about the following:

- Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;
- Technical capabilities each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product; or
- System attributes that are necessary to implement the requirements established under the DSCSA.

Interested persons are requested to provide any other relevant information that may assist with FDA’s development of a pilot project under the DSCSA.

Dated: April 11, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–08681 Filed 4–14–16; 8:45 am]
and/or hospital facilities to ensure patient safety during surgical procedures where these devices are used; and (4) appropriate guidelines and/or criteria based on a risk stratification schema for notifying patients who may have already been exposed to NTM during prior cardiac surgeries. Recommendations on these issues will assist FDA in minimizing patient exposure to infections that may result from contaminated heater-cooler devices. 

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 is 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 19, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on June 2, 2016, and between approximately 9 a.m. and 10 a.m. on June 3, 2016. 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 11, 2016. 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 12, 2016.

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

FDA is establishing a docket for public comment on this document. The docket number is FDA–2016–N–1126. The docket will close on June 16, 2016. Comments received on or before May 19, 2016, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

For press inquiries, please contact the Office of Media Affairs at fdaom@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 AnnMarie Williams, at AnnMarie.Williams@fda.hhs.gov, or 301–796–5966, 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 12, 2016.

Jill Hartzler Warner, Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–08737 Filed 4–14–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1113]

Data Integrity and Compliance With Current Good Manufacturing Practice; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Data Integrity and Compliance With CGMP.” The purpose of the draft guidance is to clarify the role of data integrity in current good manufacturing practice (CGMP) for drugs. The draft guidance is in response to an increase in CGMP violations involving data integrity observed in recent CGMP inspections. When finalized, the draft guidance is intended to provide the Agency’s current thinking on the creation and handling of data in accordance with CGMP requirements.