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 FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and 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: The committee will discuss new drug application (NDA) 209445, cefiderocol lyophilized powder for intravenous administration, submitted by Shionogi Inc., for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis due to gram-negative bacteria in patients with limited or no alternative treatment options.

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 website 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 website after the meeting. Background material is available at *https://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. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before October 1, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 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 September 23, 2019. 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 September 24, 2019.

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

For press inquiries, please contact the Office of Media Affairs at *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 Lauren Tesh Hotaki (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17934 Filed 8–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–0466]

Determination That Dextrose, 20 Grams/100 Milliliters, and Dextrose, 50 Grams/100 Milliliters, in Plastic Containers, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Dextrose, 20 grams (g)/100 milliliters (mL), and Dextrose, 50 g/100 mL, in plastic containers, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Heather A. Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–348–3946, *Heather.Dorsey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers, are the subject of NDA 017521, held by Baxter Healthcare Corporation and initially approved on August 28, 1979. Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers, are indicated as a source of calories when mixed with amino acids or other compatible intravenous fluids for patients requiring parenteral nutrition when oral or enteral nutrition is not

possible, insufficient, or contraindicated.

Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Fresenius Kabi USA, LLC, submitted a citizen petition dated January 29, 2019 (Docket No. FDA–2019–P–0466), under 21 CFR 10.30, requesting that the Agency determine whether Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17874 Filed 8–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

Implementing the Food and Drug Administration's Predictive Toxicology Roadmap: An Update of the Food and Drug Administration's Activities; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Implementing FDA's Predictive Toxicology Roadmap: An Update of FDA's Activities.'' The purpose of the public workshop is to highlight the work FDA has been doing to support and implement FDA's Predictive Toxicology Roadmap.

DATES: The public workshop will be held on September 18, 2019, from 8 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), 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.*

FOR FURTHER INFORMATION CONTACT: Laurie-Anne Sayles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4355, Silver Spring, MD 20993, 301–796–0621 x4353, *Laurie-Anne.Sayles@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In December 2017, FDA launched its Predictive Toxicology Roadmap, a six-part framework for integrating predictive toxicology methods into safety and risk assessments. Among other recommendations, the Roadmap calls for FDA research to identify data gaps and to support intramural and extramural research to ensure that the most promising technologies are developed, validated, and integrated into regulatory review, if applicable.

FDA held its initial public hearing on the Roadmap, sponsored by FDA's cross-agency Toxicology Working Group, on September 12, 2018. More information about the Roadmap as well as the initial public hearing can be found on the following website: *https://www.fda.gov/predictivetoxroadmap.*

II. Topics for Discussion at the Public Workshop

On Wednesday, September 18, 2019, FDA will highlight the work it has been doing to support and implement FDA's Predictive Toxicology Roadmap.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/predictivetoxroadmap.*

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by Monday, September 16, 2019, 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Laurie-Anne Sayles (see **FOR FURTHER INFORMATION CONTACT**) no later than September 11, 2019, 5 p.m. Eastern Time.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. To register for the webcast, please visit the following website: *https://www.fda.gov/predictivetoxroadmap.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.fda.gov/predictivetoxroadmap.*

Dated: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17876 Filed 8–19–19; 8:45 am]

BILLING CODE 4164–01–P