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the Agency determine whether Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), were withdrawn from sale for reasons of safety or effectiveness.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under § 314.161 that Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers (NDA 017521), were not withdrawn for reasons of safety or effectiveness.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data or other information suggesting that Dextrose, 20 g/100 mL, and Dextrose, 50 g/100 mL, in plastic containers, were withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.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]

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