

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 2, 2017. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 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 April 24, 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 April 25, 2017.

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

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 Rakesh Raghuwanshi 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 18, 2017.

Anna K. Abram,

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

[FR Doc. 2017-08177 Filed 4-21-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Reducing the Risk of Preventable Adverse Drug Events Associated With Hypoglycemia in the Older Population; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), Professional Affairs and Stakeholder Engagement Staff (PASES), is announcing a 1-day public workshop entitled "Reducing the Risk of Preventable Adverse Drug Events Associated with Hypoglycemia in the Older Population." The purpose of this workshop is to discuss the importance of individualized glycemic control targets for older patients with diabetes; to reduce the risk of serious hypoglycemia; identify and discuss medication safety efforts, both those that are part of the Safe Use Initiative and those external to FDA, that are of direct relevance and importance to older patients living with the disease; discuss future areas of research which could be explored to reduce the risk of serious hypoglycemia in older diabetic patients; and disseminate the results of this discussion to inform patients, patient advocates, and health care practitioners.

DATES: The public workshop will be held on September 12, 2017, from 9 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), 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 <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Scott Winiecki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-8824, email: CDERSafeUseInitiative@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA CDER, PASES, is announcing a 1-day public workshop entitled "Reducing the Risk of Preventable Adverse Drug Events associated with Hypoglycemia in the Older Population." The purpose of this workshop is to: (1) Discuss the importance of individualized glycemic control targets for older patients with diabetes, in order to reduce the risk of serious hypoglycemia; (2) identify and discuss medication safety efforts, both those that are part of the Safe Use Initiative and those external to FDA, that are of direct relevance and importance to older patients living with the disease; (3) discuss future areas of research which could be explored to reduce the risk of serious hypoglycemia in older diabetic patients; and (4) disseminate the results of this discussion to inform patients, patient advocates, and health care practitioners.

II. Topics for Discussion at the Public Workshop

The symposium will feature presentations on the scope of hypoglycemia-related adverse drug events in the older population, the risks and benefits of various degrees of glycemic control, factors affecting patient centered care, research into effective diabetes management, and the concept and translation of individualized glycemic targets to minimize adverse events in practice settings. Presenters will represent multidisciplinary backgrounds from government, academia, patient safety groups, health care industry, and clinicians. There will be opportunities for collaboration between speakers and attendees as well as question and answer sessions.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site: <http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm538666.htm?SSContributor=true>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 29, 2017, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit,

onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

For those without Internet access, please contact Scott Winiecki, (see **FOR FURTHER INFORMATION CONTACT**) to register. If you need special accommodations due to a disability, please contact Scott Winiecki no later than September 1, 2017.

Transcripts: A transcript of the public workshop will be accessible at <https://www.regulations.gov> approximately 30 days after the workshop. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 18, 2017.

Anna K. Abram,

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

[FR Doc. 2017-08178 Filed 4-21-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0179]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may send proposed agendas to the Agency by June 23, 2017.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993-0002, 301-796-0578, dan.brum@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of

the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's

Office of Regulatory Affairs District Offices in the firms' respective regions. Firms that want to learn more about this training opportunity or that are interested in offering a site tour should respond by sending a proposed agenda by email directly to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: April 17, 2017.

Anna K. Abram,

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

[FR Doc. 2017-08183 Filed 4-21-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidance for Naloxone Hydrochloride; New Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a new draft guidance for industry on generic naloxone hydrochloride nasal spray entitled "Draft Guidance on Naloxone Hydrochloride." The new draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for naloxone hydrochloride nasal spray.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final versions of the guidance, submit either electronic or written comments on the draft guidances by June 23, 2017.

ADDRESSES: 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 comment will be made public, you are solely responsible for ensuring that your