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.

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