4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Sixth Annual Coalition Against Major Diseases/Food and Drug Administration Scientific Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the sixth annual scientific workshop co-sponsored by the Agency and the Coalition Against Major Diseases (CAMD) Consortium of the Critical Path Institute (C-Path). The purpose of this public workshop is to initiate constructive discussion among scientists from FDA, the CAMD Consortium, and other interested parties regarding ongoing efforts to develop tools and methods to facilitate drug development for Alzheimer's disease and Parkinson's disease.

DATES: The public scientific workshop will be held on October 15, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public scientific 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: Jacqueline Brooks-Leighton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, rm. 4521, Silver Spring, MD 20993, 240-402-5292, FAX: 301-796-9907, jacqueline.brooks-leighton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and C-Path seek to leverage their combined strengths to create new tools and methods to increase the efficiency of the drug development process and bring new treatments for Alzheimer's disease and Parkinson's disease. This annual public workshop brings together representatives from the pharmaceutical industry, the academic research community, patient advocacy groups, and governmental institutions; including, the National Institute of Aging, the National Institute of Neurological Disorders and Stroke, and the European Medicines Agency.

The objectives of the workshop include:

1. Understanding the accomplishments of CAMD scientific projects
2. Discussing how these tools are currently or will be applied in drug development
3. Obtaining commitment for sharing information/data to begin quantifying benefits of these tools
4. Facilitating robust and open discussion among all parties of drug development in Alzheimer's and Parkinson's diseases

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to participate in the scientific workshop (in person or via the Internet) must register on or before October 1, 2015, by visiting https://www.SignUp4.net/public/ap.aspx?EID=SIXT10E.

Early registration is recommended; registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the scientific workshop will be based on space availability. The registration deadline is October 14, 2015. An agenda will be provided approximately 2 weeks before the scientific workshop at the FDA Meeting Information page, which is available online at: http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm.

If you need special accommodations because of a disability, please contact Jacqueline Brooks-Leighton (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the scientific workshop.

A live webcast of this scientific workshop will be viewable at Adobe Connect Link: https://collaboration.fda.gov/camd101515/ on the day of the scientific workshop. A video record of the scientific workshop will be available at the same Web address for 1 year.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of

Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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