4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration /European Medicines Agency Orphan Product Designation and Grant Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting: Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Workshop. This 1-day workshop is intended to provide valuable information about the FDA and European Medicines Agency (EMA) Orphan Drug Designation programs, the FDA Humanitarian Use Device (HUD) Designation program, the FDA Orphan Products Grant program, and the European Union (EU) rare disease research programs to participants representing pharmaceutical, biotechnology, and device companies, as well as academics.

Date and Time: The meeting will be held on October 12, 2012, 8:30 a.m. to 5:30 p.m.

Attendance: Online registration for the workshop will be limited to 240 participants for the morning session, of which approximately 30 teams (up to 90 participants) may register for the one-on-one sessions. There will be no registration fee for the workshop.

Location: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD 20993-0002. Entrance for the public meeting 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 participants who cannot attend the morning meetings, simultaneous live interactive Webcasts will be made available. Participants may access the drug and biologics webcast by visiting the following site: https://collaboration.fda.gov/orphan2012/. The medical devices webcast can be accessed by visiting: https://collaboration.fda.gov/devices2012/.

Contact: Erica K. McNeilly at Erica.McNeilly@fda.hhs.gov or J. Lloyd Johnson at Lloyd.Johnson@fda.hhs.gov, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5279, Silver Spring MD 20993-0002, (301) 796-8660, FAX: (301) 847-8621.

Registration: Interested participants may register for this meeting at the following website: https://events-support.com/events/FDA-EMA_Workshop

If you need sign language interpretation during this meeting, please contact Erica K.McNeilly at Erica.McNeilly@fda.hhs.gov by September 28, 2012.

The workshop will consist of two simultaneous morning sessions. The first will provide an overview of the EMA and FDA Orphan Drug Designation programs, while the second will provide an overview of the FDA HUD Designation Program. Both morning sessions will also cover the Orphan Products Grant Program and the EU rare

disease research programs as it relates to drugs and biologics, and devices, respectively. Both of these morning sessions will also be available by webcast.

The afternoon session will provide an opportunity for appropriately registered on-site participants to have one-on-one meetings with FDA or EMA staff members to discuss the specifics on how to apply for an orphan product grant, EU rare disease research assistance program, a HUD designation, or orphan drug designation. Participants requesting one-on-one meetings will need to undergo a second registration process with FDA, and are expected to bring information for at least one candidate orphan drug or device that holds promise for the treatment of a rare disease or condition in order to discuss the processes for putting together an application. In addition, participants of the HUD or orphan drug designation one-one-one sessions are highly encouraged to come prepared with a working draft submission of their particular promising therapy in order to maximize the utility of the one-on-one meetings.

The FDA/EMA Orphan Product Designation and Grant Workshop is supported by the FDA and the EMA, and is being conducted in partnership with the European Organisation for Rare Disease (EURODIS), Genetic Alliance, and the National Organization for Rare Diseases (NORD).

Dated: August 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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