4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Scientific Evidence in Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) is announcing a public workshop entitled "Scientific Evidence in Development of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Subject to Premarket Approval. The purpose of the public workshop is to identify and discuss scientific considerations and challenges to help inform the development of HCT/Ps subject to premarket approval, including stem cell-based products.

DATES: The public workshop will be held on September 8, 2016, from 8:30 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD, 20993-0002. 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: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

The purpose of the public workshop is to identify and discuss scientific considerations and challenges to help inform the development of HCT/Ps subject to premarket approval, including stem cell-based products.

Elsewhere in this issue of the Federal Register, FDA is announcing the rescheduling of a part 15 public hearing to September 12 and 13, 2016, to obtain input on four issued draft guidance documents relating to the regulation of HCT/Ps. FDA will provide a summary of the workshop at the part 15 public hearing.

REGISTRATION: Persons (including FDA employees) seeking to view the public workshop via Adobe Connect or who wish to attend in person must register at http://www.eventbrite.com/o/food-amp-drug-administration-fda-6730245227 on or before August 1, 2016, and provide complete contact information, including name, title, affiliation, email, and phone number. There is no registration fee for the public workshop. Early registration is recommended because seating is limited and is on a first-come, first-served basis. There will be no onsite registration.

If you need special accommodations due to a disability and/or have registration questions, please contact Tasha Johnson or Pauline Cottrell at CBERPublicEvents@fda.hhs.gov (Subject line: FDA SEDHC workshop).

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at:

http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm492499.htm.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-09373 Filed: 4/21/2016 8:45 am; Publication Date: 4/22/2016]