This document is scheduled to be published in the
Federal Register on 02/12/2014 and available online at
http://federalregister.gov/a/2014-03015, and on **FDsys.gov**

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a public workshop entitled "Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products." The purpose of the public workshop is to bring together a broad range of stakeholders to discuss current and future standards development activities involving cellular therapies and regenerative medicine products. This public workshop is being rescheduled due to the government shutdown.

Date and Time: The public workshop will be held on March 31, 2014, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503 A), 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. Please visit the following Website for location, parking, security, and travel information: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Sherri Revell, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, email: CBERPublicEvents@fda.hhs.gov (Subject line: SESDCTRMP Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Sherri Revell (see Contact Person) or email to CBERPublicEvents@fda.hhs.gov (Subject line: SESDCTRMP Workshop Registration) by March 24, 2014. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

Streaming Webcast of the Public Workshop: For those unable to attend in person, FDA will Webcast the public workshop. To join the Webcast of the public workshop, please go to: https://collaboration.fda.gov/sesdctrmpworkshop/. If you have never attended an Adobe Connect meeting before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. Get a quick overview: http://www.adobe.com/go/connectpro_overview. Registration is not required for those attending via Adobe Connect.

If you need special accommodations due to a disability, please contact Sherri Revell (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Standardization efforts concerning the clinical development of cellular therapies and regenerative medicine products have generated a great deal of interest. These efforts include standards development, expert opinion position papers, and professional practice guidelines. However, relatively little is done to coordinate the various

existing efforts. In the public workshop, FDA hopes to bring together a broad range of stakeholders of cellular therapies and regenerative medicine products in order to:

- Inform stakeholders about the types of standards and standards organizations that are available currently, the role that the Federal Agencies play in standards development, and the potential role that stakeholders can play in standards development.
- Provide a high-level overview of current standards development activities in the fields of cellular therapy and regenerative medicine and the regulatory application of standards.
- Provide opportunity for discussion of areas of high interest for current or future standards development in the fields of cellular therapy and regenerative medicine and to explore ways to minimize redundancy and maximize collaboration.

We encourage all who have an interest in the development of cellular therapies and regenerative medicine products to attend the public workshop.

This public workshop is being rescheduled due to the government shutdown. It was originally scheduled for October 7, 2013 (see 78 FR 43889, July 22, 2013). Those who registered for the original workshop date must register again for the rescheduled date (see Registration).

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/TranscriptsMinutes/default.htm. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-03015 Filed 02/11/2014 at 8:45 am; Publication Date: 02/12/2014]