4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Statistical Process Controls for Blood Establishments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Statistical Process Controls for Blood Establishments." The purpose of this public workshop is to discuss the implementation of statistical process controls to validate and monitor manufacturing processes in blood establishments. The public workshop has been planned in partnership with the AABB, America's Blood Centers, and the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health. The public workshop will include presentations and discussions led by experts from government and industry.

Dates and Times: The public workshop will be held on October 19, 2012, from 8:30 a.m. to 5:00 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, The Great Room, Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD, 20993. Please visit the following Web site for location, parking, security, and travel information: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm. The public workshop will also be available to be viewed online via webcast.

Streaming Webcast of the Public Workshop: For those unable to attend in person, FDA will webcast the public workshop. To join the web-cast of the public workshop, please go to: https://collaboration.fda.gov/stat101912/.

If you have never attended a Connect Pro meeting before:

Test your connection: https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.

Get a quick overview: http://www.adobe.com/go/connectpro_overview.

Contact Person: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6128, FAX: 301-827-2843, e-mail: CBEROBRRWorkshops@fda.hhs.gov.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see Contact Person) by September 27, 2012. Please indicate if you will attend the workshop in person or if you will participate in the webcast. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Those who wish to present at the workshop must attend in person. Registration on the day of the public workshop will be provided on a space-available basis beginning at 7:30 a.m.

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

Requests for Oral Presentations: Interested persons are invited to make presentations relevant to the public workshop topic. Attendees who wish to make presentations at the public workshop should notify the Contact Person and submit a brief statement of the general nature of the presentation before September 27, 2012. Presentations will be scheduled on the afternoon of

October 19, 2012. Time allotted for each presentation may be limited depending on the number of individuals requesting to speak.

SUPPLEMENTARY INFORMATION:

Statistical process control is the application of statistical methods to the monitoring, or quality control, of a manufacturing process. The implementation of acceptable statistical process controls ensures that a process performs predictably to manufacture a product that meets specific standards. FDA monitors manufacturing procedures, validation summaries, and quality control data prior to licensure and during periodic inspection of facilities.

Millions of units of Whole Blood and blood components, including those collected by apheresis, are manufactured in the United States annually. Blood establishments manufacture these products in accordance with specific standards established by FDA regulations and guidance, as well as in accordance with specifications established by device manufacturers and industry standards. To ensure that product standards are met, blood establishments validate manufacturing processes at implementation and then monitor these processes on a regular basis, using quality control methods.

Manufacturing biologic products, including Whole Blood and blood components, comes with specific challenges due to biologic variability and the potential risk to recipients if products are not manufactured appropriately. Recognizing these issues, FDA has developed statistical plans that are capable of identifying when the manufacturing process varies or has a high frequency of nonconformance.

The goal of the workshop is to educate participants on statistical process control theory and options for the implementation of scientifically sound sampling plans in blood

establishments. The public workshop will include presentations and discussions on the following topics: (1) The evolution of statistical process control for Whole Blood and blood components; (2) statistical methods used for biologic product quality control; (3) FDA considerations for sampling plans for blood establishments; and (4) industry perspectives and case studies on implementing statistical process controls.

Transcripts: Please be advised that a transcript of the public workshop will be posted as soon as possible on the Internet 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., Rockville, MD 20857.

Dated: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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