4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures; 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: "Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures." The purpose of this public workshop is to provide stakeholders a forum for discussion of data needs and to obtain feedback on possible modeling scenarios to explore emergency supply situations should a pandemic or epidemic disease or other events that could adversely impact the blood supply in the United States occur.

The public workshop will include presentations and panel discussions with experts from academia, regulated industry, government, and other stakeholders.

Date and Time: The public workshop will be held on July 24, 2012, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Ave, Bethesda, MD 20814, 301-657-1234.

Contact Person: Mark Walderhaug, Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6028, email: Mark.Walderhaug@fda.hhs.gov.

Registration: Mail or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to Mark Walderhaug (see Contact Person) by July 17, 2012. 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 8 a.m.

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

SUPPLEMENTARY INFORMATION:

The public workshop presentations and panel discussions will: (1) Discuss simulation modeling of the U.S. blood supply, including the possible application of an FDA computer simulation model of the U.S. blood supply in support of emergency preparedness and planning for potential disruptions in blood donations; (2) discuss with the blood community the utility of simulation methods as a complementary approach to support planning for daily inventory needs and forecasting for future blood donations and demand; (3) discuss the capabilities and limitations of the U.S. computer simulation model, assumptions used in the model and data gaps for model validation; (4) describe and prioritize future model enhancements to extend the model predictions from red blood cell units to other blood components, such as plasma and platelets; and (5) discuss the level of detail required for a model to characterize the U.S. blood supply and to develop possible scenarios in which shortages may be addressed through countermeasures such as the use of local and interregional transfers of blood and blood components.

Transcripts: Transcripts of the public workshop may 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, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at: http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.

Dated: May 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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