

Dated: July 7, 2009.

Elaine L. Baker,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0284]

Food and Drug Administration Regulation and Licensure of Whole Blood and Blood Components, Including Source Plasma; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "FDA Regulation and Licensure of Whole Blood and Blood Components, Including Source Plasma." The purpose of the workshop is to educate industry on the licensure requirements and license application procedures for Whole Blood and blood components, including Source Plasma, and request comments on this topic.

Dates and Time: The public workshop will be held on September 15, 2009, from 8 a.m. to 5:30 p.m. and September 16, 2009, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at The Universities at Shady Grove Conference Center, 9630 Gudelsky Dr., Bldg. 1, Rockville, MD 20850.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 400N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: rhonda.dawson@fda.hhs.gov.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person (see *Contact Person*) by August 17, 2009. 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.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance of the workshop.

Comments: All individuals wishing to submit questions to be addressed at the public workshop should submit written or electronic comments by August 17, 2009, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: FDA held a licensing workshop for blood establishments in 1995 to advise the blood and plasma industry on how to apply for a U.S. license to distribute Whole Blood and blood components, including Source Plasma, in interstate commerce. This workshop will build upon the 1995 workshop and provide regulatory updates since the last workshop. The workshop will include presentations by FDA on the following topics: (1) Requirements for licensure and applicable regulations and guidance documents for Whole Blood and blood components, including Source Plasma; (2) managed review process; (3) review criteria for various submissions; (4) blood establishment registration and product listing requirements; (5) inspections of blood establishments pending licensure and approval; and (6) requests for exceptions or use of alternative procedures to the regulations. The workshop will include a question and answer session with workshop participants.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, 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/cber/minutes/workshop-min.htm>.

Dated: July 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 8 a.m.-4 p.m., July 29, 2009.

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent "Oz" Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. Section 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: The agenda will include discussions related to recommendations for use of influenza vaccines in the prevention and control of novel (pandemic) influenza A (H1N1); novel H1N1 epidemiology in the United States; novel H1N1 epidemiology, international settings; modeling novel H1N1 influenza impact and impact of vaccination; implementation planning; vaccine development and formulation; and the Food and Drug Administration/Vaccines and Related Biological Products Advisory Committee update. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Antonette Hill, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., Mailstop E-05, Atlanta, Georgia 30333, Telephone: (404) 639-8836, Fax: (404) 639-8905.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and Agency for Toxic Substances and Disease Registry.

Dated: July 6, 2009.

Elaine L. Baker,

*Director, Management Analysis and Services
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Prevention.*

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