

background information on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. The revised agenda also will include the workgroup report on specimens and test systems not currently regulated under CLIA, the criteria and process for waiver, and updates from CDC, Food and Drug Administration and Health Care Financing Administration.

The Committee solicits oral and written testimony on specimens and test systems not currently regulated under CLIA. Requests to make an oral presentation should be submitted in writing to the contact person listed below by close of business, September 20, 2000. All requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and should be received by the contact person listed below by close of business, September 20, 2000.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Rhonda Whalen, Acting Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, Mailstop F-11, Atlanta, Georgia 30341-3724, telephone 770/488-8042, fax 770/488-8279.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 6, 2000.

Carolyn J. Russell,

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

[FR Doc. 00-24106 Filed 9-19-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Streamlining the Blood Donor History Questionnaire; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop

entitled "Streamlining the Blood Donor History Questionnaire." The purpose of the public workshop is to streamline the blood donor history questionnaire without compromising the safety of the nation's blood supply. The public workshop is jointly sponsored by FDA and the American Association of Blood Banks.

Date and Time: The public workshop will be held on October 16, 2000, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Lister Hill Conference Center, National Institutes of Health, Building 38A, 8600 Rockville Pike, Bethesda, MD 20894.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (address above) by Friday, October 6, 2000. There is no registration fee for the public workshop. Seating is limited, therefore interested parties are encouraged to register early. Registration at the site will be done on a space available basis on the day of the public workshop, beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The public workshop is expected to address, but is not limited to, the following issues and topics: (1) The role of the blood donor interview in assuring blood safety; (2) overview of past efforts to improve the donor history questionnaire; (3) different methodologies in performing donor history evaluations; (4) validating the donor history questionnaire as a tool for reducing and eliminating risks to the blood supply; (5) analysis of error and accident reports and post donation information that resulted from inaccurate or misleading donor history responses; and (6) suggestions on how the donor questionnaire can be streamlined without compromising either donor, product, or recipient safety.

The public workshop agenda will be posted on the FDA Internet as soon as the information becomes available. The FDA Internet address is <http://www.fda.gov/cber/whatsnew.htm>.

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. 12A-16, Rockville, MD 20857,

approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on the FDA Internet site at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: September 14, 2000.

William K. Hubbard,

Senior Associate, Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-24124 Filed 9-19-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Evaluation of New Vaccines: How Much Safety Data?; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: "Evaluation of New Vaccines: How Much Safety Data?" The purpose of the workshop is to address issues in the safety evaluation of new vaccines, including the feasibility and desirability of performing larger pre-licensure trials of vaccines in order to provide more precise measures of safety prior to widespread use, and to discuss the optimal balance between pre-licensure and post-licensure evaluation of vaccine safety.

Date and Time: The workshop will be held on November 14, 2000, from 1 p.m. to 5:30 p.m. and on November 15, 2000, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Lister Hill Conference Center, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20814.

Contact:

For information regarding this notice: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210, FAX 301-827-1944.

For information regarding the workshop: Mary A. Foulkes, Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3034, FAX 301-827-3529.

For registration information: Sandy L. Coffin, Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-