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**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.

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*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, 301-827-3034, FAX 301-827-3529, or e-mail: coffins@cber.fda.gov.

*Registration:* Send or fax your registration form (including name, title, firm name, address, telephone, fax number, and e-mail address) to the Sandy L. Coffin (address above) by Friday, October 20, 2000. There is no registration fee for the workshop, however, seating is limited. Therefore, interested parties are encouraged to register early.

You may get a copy of the registration form and additional information about this workshop from the Internet at <http://www.fda.gov/cber/meetings/vac111400.htm>.

If you need special accommodations due to a disability, please contact Sandy L. Coffin (address above) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** This workshop is cosponsored by the following organizations: FDA, Center for Biologics Evaluation and Research; National Institutes of Health, National Institute of Allergy and Infectious Diseases; Centers for Disease Control and Prevention (CDC); Health Resources and Services Administration; and National Vaccine Program Office, CDC. The workshop will be of primary interest to public health professionals evaluating new vaccines and to vaccine manufacturers developing new vaccines. The objectives of the workshop are to: Describe the evolution of new vaccine evaluation and the current approaches to postmarketing safety evaluation, discuss public concerns about vaccine safety, and explore alternatives for enhancing postmarketing safety evaluation and the value and feasibility of larger pre-licensure trials.

*Transcripts:* Transcripts of the meeting 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 at the Center for Biologics Evaluation and Research Internet site at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: 9/14/00  
September 14, 2000



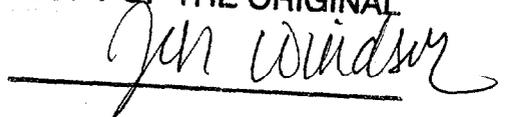
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William K. Hubbard  
Senior Associate  
Commissioner for Policy, Planning, and Legislation

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