

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Immune Correlates of Protection Against Influenza A Viruses in Support of
Pandemic Vaccine Development; 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 “ Immune Correlates of Protection against Influenza A Viruses in Support of Pandemic Vaccine Development.” The purpose of the public workshop is to identify the gaps in our knowledge and abilities in addressing the unique challenges encountered in the development and evaluation of vaccines intended to protect against pandemic influenza.

Date and Time: The public workshop will be held on December 10, 2007, from 8:30 a.m. to 5:30 p.m. and December 11, 2007, from 8 a.m. to 5:15 p.m.

Location: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. For directions, see the hotel Web site at: <http://www.bethesda.hyatt.com> or call the hotel at 301-657-1234.

Contact Person: Maureen Hess, Center for Biologics Evaluation and Research (HFM-405), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5113, FAX: 301-827-9781, e-mail: maureen.hess@fda.hhs.gov.

Registration: E-mail or fax your registration information (including name, title, firm name, address, telephone, fax number and e-mail address) to the

contact person by November 19, 2007. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

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

SUPPLEMENTARY INFORMATION: FDA's Center for Biologics Evaluation and Research, in cooperation with the National Institutes of Health's Division of Intramural Research within the National Institute of Allergy and Infectious Diseases and the World Health Organization, is holding this public workshop. The public workshop will include discussions on: (1) Current knowledge regarding correlates of protection against seasonal influenza, (2) immune responses to avian influenza infections and vaccines for novel influenza viruses in humans, (3) assays to evaluate vaccine immunogenicity, and (4) evaluation of avian influenza vaccine efficacy. The goals of the public workshop are to: (1) Identify the gaps in our knowledge and abilities in addressing the unique challenges encountered in the development and evaluation of vaccines intended to protect against pandemic influenza, and (2) facilitate implementation of a global research agenda to improve efficacy assessment of pandemic influenza vaccines.

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: October 18, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins