

not established and billed before October 1, 2007, and that there will be a gap between the start of the fiscal year and the date that fees are due. However, the voluntary submission of a DTC television advertisement for FDA advisory review on or after October 1, 2007, but before November 26, 2007 will be considered by FDA as notification that the company who submitted the advertisement wishes to participate in the program and agrees to pay the advisory review fee and operating reserve fee for each such submission in a timely manner once the fees for FY 2008 are established and the company is invoiced. Companies who submit DTC television advertisements for advisory review in this period should respond to this participation notice, and include any such submissions in their count of the total number of advisory submissions they intend to submit in FY 2008. FDA will also contact companies who submit DTC television advertisements in this time period to request written confirmation from these companies of their commitment to pay these fees; if companies do not agree to make this commitment, FDA will request that they withdraw their submission(s), and such submissions will not be reviewed. For companies who do agree, FDA will begin its advisory review of a complete submission of a DTC television advertisement for advisory review on the date that it receives written confirmation of the company's commitment to pay the fees associated with the submission in a timely manner once the company is invoiced.

For information on how FDA will treat DTC television advertisement advisory review submissions not identified in response to this notice that are submitted after November 26, 2007, see sections IV.C "Additional Submissions" and IV.E "Operating Reserves" of this document.

Dated: October 19, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 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](mailto: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,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0396]

#### Draft Guidance for Industry on Drug-Induced Liver Injury: Premarketing Clinical Evaluation; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation." This guidance is intended to assist the pharmaceutical industry and others engaged in new drug development in the assessment of the potential of a drug to cause severe drug-induced liver injury (DILI). This guidance defines severe DILI as injury that is fatal or requires liver transplantation. This guidance does not address the postmarketing evaluation of DILI.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 24, 2007.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,