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.

[FR Doc. 07–5282 Filed 10–24–07; 8:45 am]

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*.

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.

[FR Doc. E7–20981 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

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,

Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidance may also be obtained from the Center for Biologics Evaluation and Research by mail by calling 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Tom Moreno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5143, Silver Spring, MD 20993–0002, 301–796–0878; or

Bruce Schneider, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5102.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation.'' Idiosyncratic hepatotoxicity is an important cause of drug withdrawal and has led to considerable FDA attention to the subject, beginning with a conference on hepatotoxicity at the National Institutes of Health in 1978. The science of detecting and evaluating DILI during drug development is evolving, and FDA is working with industry, academia, and other government groups toward better understanding of the problems and what to do about them.

Even drugs that prove to be significant hepatotoxins (e.g, bromfenac and troglitazone) are unlikely to show cases of severe DILI during a drug development program with at most several thousand exposed subjects. Therefore, it is critical during drug development to discover less severe DILI that may indicate a potential for the drug to cause severe DILI. There are a number of signals of liver injury that have varying levels of sensitivity and specificity in predicting potential for severe DILI. An increased rate of elevated aminotransferase (AT) levels compared to control is a highly sensitive indicator of potential severe hepatotoxicity, but many drugs that do not cause severe injury show AT elevations, so the specificity of this test as a predictor of a potential for severe hepatotoxicity is poor. Specificity is increased when the signal used is the occurrence of more marked AT elevation (to 5-, 10-, 20xULN), but the most specific finding to date is an overall pattern of AT elevation together with elevated bilirubin (and no evidence of bile obstruction) in a small number of subjects.

This guidance describes the sensitivity and specificity of various indicators of hepatotoxic potential, as well as the observations needed to evaluate those indicators, including detection, confirmation, and monitoring of liver test abnormalities, close evaluation and exclusion of other causes, and careful supportive care and followup to normality or return to baseline status.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on premarketing clinical evaluation of drug-induced liver injury. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312, 314, and 600 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 19, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21060 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0387]

Draft Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic Device Studies—Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Draft Guidance for Industry and FDA Staff; In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions.'' This draft guidance document contains information to assist manufacturers in developing and conducting studies for IVD devices, particularly those exempt from most of the Investigational Device Exemption (IDE) regulations. This draft guidance is neither final nor is it in effect at this time.

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 before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 23, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and FDA Staff; In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that