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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128] (formerly Docket No. 2007D–0396)

Draft Guidance for Industry on Drug-Induced Liver Injury: Premarketing Clinical Evaluation; Reopening of Comment Period; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of reopening of comment period; notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 30, 2008, the comment period for the draft guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation," published in the **Federal Register** of October 25, 2007 (72 FR 60681). FDA is also announcing a public conference entitled "Detecting and Investigating Drug-Induced Liver Injury During Clinical Trials." FDA is cosponsoring the conference with the American Association for the Study of Liver Diseases (AASLD) and the Pharmaceutical and Research Manufacturers of America. The purpose of the conference is to discuss the draft guidance and to solicit additional input on the issues and questions presented in this document.

DATES: The public conference will be held on March 26, 2008, from 8 a.m. to 6 p.m. and March 27, 2008, from 8 a.m. to 3 p.m. Please register by March 14, 2008, to make an oral presentation during the open public session on March 27, 2008. Submit written or electronic comments on the draft guidance, the conference program and presentations, and the issues and questions presented in this document by June 30, 2008.

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ADDRESSES: The public conference will be held at the National Labor College (NLC), 10000 New Hampshire Ave., Silver Spring, MD 20903.

Submit written comments 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comments to *http://www.regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, e-mail: *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Reopening of Comment Period for the Draft Guidance

In the **Federal Register** of October 25, 2007, FDA issued the draft guidance "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" and invited comments by December 24, 2007. This draft guidance describes methods for detecting drug-induced liver injury (DILI) that may occur during the course of conducting controlled clinical trials. To provide interested persons additional time to review the draft guidance and submit comments, the agency is reopening the comment period until June 30, 2008.

II. The Public Conference

A. Why Are We Holding This Public Conference?

The purpose of the conference is to discuss the draft guidance and issues that it may raise and to solicit additional input on the issues and questions presented in this document.

B. What Are the Topics We Intend to Address at the Conference?

We hope to discuss a large number of issues at the conference, including, but not limited to:

- The approach to detecting the potential for severe DILI described in the draft guidance;
- What stopping rules should govern the administration of an investigational agent during a clinical trial;
- When should rechallenge of a suspected injurious agent be considered;
- Should patients or study participants with stable chronic liver disease be included in clinical trials; and
- Other issues and questions raised by the conference attendees or others.

C. Is There a Fee and How Do I Register for the Conference?

There is a modest fee to attend the conference, to defray the costs of meals provided, rental of the NLC meeting facility, travel expenses for invited academic (but not government or industry) speakers, and other expenses. The fee for the 2-day meeting for registrants from industry is $350, and the fee for academic or government registrants is $175. Fees will be waived for invited speakers and moderators.

The registration process will be handled by AASLD, which has extensive experience in planning, executing, and organizing educational meetings. Register online at *http://www.aasld.org.* Although the NLC facility is spacious, registration will be on a first-come, first-served basis. If you would like to make an oral presentation during the open hour of the conference on March 27, 2008, you must register with Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**) by close of business on March 14, 2008. To make a presentation, you will be asked to provide your name, title, business affiliation (if applicable), address, and

type of organization you represent (e.g., industry, consumer organization). Persons registered to make an oral presentation should check in before the conference. If you need special accommodations because of a disability, please contact Lana Pauls at least 7 days before the conference.

D. Where Can I Find Out More About This Public Conference?

Background information on the conference, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cder/livertox* and *http://www.aasld.org.*

E. Conference Transcripts

We will prepare a transcript of the conference presentations and discussions and will post it online along with copies of slides shown. The transcript will be available for review on the Internet at *http://www.fda.gov/cder/livertox* approximately 30 days after the conference.

III. Comments

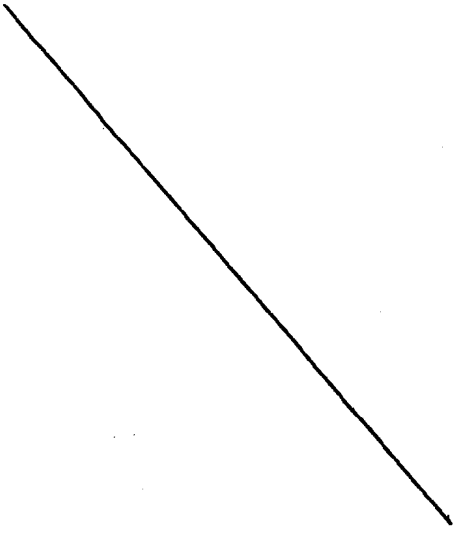
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the issues and questions presented in this document or at the conference. Submit a single copy of electronic comments or two paper copies of any mailed 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-

wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

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



Dated: 2/29/08

February 29, 2008.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

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