Health and Human Services, the central point is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517–D, 200 Independence Avenue, SW Washington, DC 20201.

Certification Regarding Drug-Free Workplace Requirements (Instructions for Certification)

(1) By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

(2) The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

(3) For grantees other than individuals, Alternate I applies.

(4) For grantees who are individuals, Alternate II applies.

(5) Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

(6) Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

(7) If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

(8) Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All direct charge employees; (ii) All indirect charge employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements

Alternate I. (Grantees Other Than Individuals)

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(1) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(2) Establishing an ongoing drug-free awareness program to inform employees about—

(a) The dangers of drug abuse in the workplace;

(b) The grantee's policy of maintaining a drug-free workplace;

(c) Any available drug counseling, rehabilitation, and employee assistance programs; and

(d) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(3) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(4) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(a) Abide by the terms of the statement; and

(b) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(5) Notifying the agency in writing, within 10 calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(6) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted—

(a) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(b) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(7) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Check if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

(1) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(2) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0143] (formerly Docket No. FDA–2008–D–0128)

Guidance for Industry on Drug-Induced Liver Injury: Premarketing Clinical Evaluation; Opening of Comment Period for Future Revision of Guidance Dated July 2009; Public Conference

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) is opening a comment period for submission of suggestions for revising the guidance for industry published in the **Federal**

Register July 30, 2009, entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation." In addition, FDA, along with the American Association for the Study of Liver Diseases (AASLD) and the Pharmaceutical and Research Manufacturers of America, is sponsoring a public conference to be held on March 24 and 25, 2010, to discuss and debate issues contained in the published guidance document. The purpose of the conference is to consider the effect of the recommendations in the guidance since its publication, and to seek suggestions for future revisions that will incorporate the views expressed.

DATES: The public conference will be held on March 24, 2010, from 8 a.m. to 6 p.m. and March 25, 2010, from 8 a.m. until 3:15 p.m. Submit written or electronic comments on agency guidances at any time.

ADDRESSES: The conference will take place at the National Labor College, 10000 New Hampshire Ave., Silver Spring MD 20993.

Submit written requests for single copies of the July 2009 guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4307, Silver Spring MD 20993–0002, 301–796–0518, e-mail: *lana.pauls@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced in July 2009 the availability of a guidance for industry entitled "Guidance for Industry on Drug-Induced Liver Injury: Premarketing Clinical Evaluation." The guidance explained that drug-induced liver injury (DILI) has been the most frequent cause of acute liver failure in the United States in the last 10 years, exceeding all other causes combined. It discussed methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration elevations, and how those laboratory tests might change over time, along with symptoms and physical findings, to allow estimation of severity of the injury. It suggested some rules for stopping or interrupting drug treatment, and the need to obtain additional clinical information to estimate the likelihood of the true cause. Previous periods for comments on the draft guidance were opened in 2007 and 2008, and those comments were taken into consideration when issuing the final guidance in July 2009. The guidance was issued consistent with FDA's good guidance practices regulation (21 CFR 10.115), representing the agency's current thinking on evidence for DILI in premarketing clinical evaluation. 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 Public Conference

A. Why Are We Holding This Conference?

The purpose of the 2010 conference is to discuss the most current information and thinking about clinical and basic aspects of the still-unsolved problems of exactly how drugs cause liver injury and why certain individual people are more susceptible than others, combining views of both basic science and clinical experts, and selecting for specific debate and discussion some controversial issues such as:

- Whether indications of cholestasis (biliary tract obstruction) are less important than evidence of primarily hepatocellular injury with secondary functional impairment;
- What findings could lead to interrupting or permanently stopping administration of new drugs under evaluation; and
- The appropriate use of rechallenge testing to study hepatotoxicity.

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

A modest registration fee will be charged to attendees other than invited speakers, to help defray the costs of rental of the meeting spaces, meals and snacks provided, and if possible to cover travel costs incurred by invited academic (but not Government or industry) speakers, and other costs. The fee for the 2-day meeting for industry registrants is $450, and $225 for Federal Government and academic registrants. Registration fees will be waived for invited speakers and moderators.

The registration process will be handled by AASLD, a not-for-profit organization which has extensive experience in planning, organizing, and executing educational meetings.

The presentations and discussions will be recorded and published on the Internet for public availability after minor editing by FDA. It will then be posted on the Internet by AASLD following the meeting, to allow consideration of the issues and material presented by those unable to attend the conference in person.

Additional information on the conference, program, and registration procedures, as well as on past conferences 2001 through 2009, is available on the Internet at *http://www.aasld.org* (go to Conferences and Education, Meetings and Conferences), and also at *http://www.fda.gov* by typing into the search box "liver toxicity." (FDA has verified the AASLD Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance and the issues and questions presented 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: March 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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