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 The draft guidance may also be obtained from the Center for Biologics Evaluation and Research by mail by calling 1–800–835–4709 or 301–827–1800.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation.''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

office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Sally Hojvat, Center for Devices and Radiological Health (HFZ–312), Food and Drug Administration,2098 Gaither Rd, Rockville, MD 20850, 301–594–5940, ext. 114; or

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to facilitate the movement of new IVD technology from the investigational stage to the marketing stage by providing information about the development and conduct of IVD studies that will be submitted to the agency to support premarket notifications and applications. Because many IVD studies are exempt from most of the IDE regulations at part 812 (21 CFR part 812) (§ 812.2(c)(3)), both industry sponsors and FDA staff often have questions concerning the relevant requirements and appropriate methods for such studies. This draft guidance provides information about such studies as well as general information about the development, conduct, and responsibilities associated with all IVD studies. The Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) both have regulatory oversight of IVD devices. Information in this draft guidance is relevant to IVD devices regulated by either center under subchapter H of 21 CFR Chapter I.

II. Significance of Guidance

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 IVD device studies. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Draft Guidance for Industry and FDA Staff; In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1587 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 PRA). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR 807.87 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 810 have been approved under OMB control number 0910–0432; the collections of information under part 812 have been approved under OMB control number 0910–0078; the collections of information in part 814 (21 CFR part 814), subparts B and E, have been approved under OMB control number 0910–0231; the collections of information in part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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.

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–0168]

Publication of Guidances for Industry Describing Product-Specific Bioequivalence Recommendations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' explaining the process that would be used to make product-specific BE recommendations available to the public on FDA's Web