

The guidance represents FDA's current thinking on this topic. 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. Paperwork Reduction Act of 1995

This 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 collections of information in the Investigational New Drug Application (IND) regulations (21 CFR part 312) have been approved under OMB control number 0910–0014; the Good Laboratory Practice regulations (21 CFR part 58) have been approved under OMB control number 0910–0119.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and 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 guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20129 Filed 11–27–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

Draft Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff on In Vitro Diagnostic Multivariate Index Assays; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period on the “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.” The agency announced the availability of this draft guidance in the **Federal Register** of September 7, 2006 (71 FR 52800). The initial comment period closes on December 6, 2006. To provide interested persons additional time to review and submit comments on the draft guidance, the agency has decided to extend the comment period.

DATES: Submit written or electronic comments on this draft guidance by March 5, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays” 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 <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food

and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0490, ext. 162.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is extending the comment period on the “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.” This draft guidance is intended to provide clarification on FDA's approach to regulation of in vitro diagnostic multivariate index assays.

The agency issued this draft guidance on September 7, 2006. The initial comment period on the draft guidance closes on December 6, 2006, but at the request of in vitro diagnostic device stakeholders, the agency has decided to extend the comment period for an additional 90 days, until March 5, 2007.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one 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.

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, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays,” 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 1610 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 Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

Dated: November 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-20032 Filed 11-27-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0468]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this notice is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by January 29, 2007.

ADDRESSES: Submit written proposed agendas regarding the Site Tours Program to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or to Beth Duvall-Miller (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993-0002, 301-796-0700.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated

various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance significantly review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Firms interested in offering a site tour or learning more about this training opportunity should respond by (see **DATES**) by submitting a proposed agenda to the Division of Dockets Management

or to Beth Duvall-Miller (see **ADDRESSES**).

Dated: November 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-20041 Filed 11-27-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: November 29, 2006, 9 a.m.-5 p.m.; November 30, 2006, 8:30 a.m.-3 p.m.

Place: Washington Marriott Hotel, 1221 22nd Street, NW., Washington, DC 20037, (202)-872-1500.

Status: The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following issues: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of pregnant women and infants, factors affecting the continuum of care with respect to maternal and child health care, and outcomes following childbirth. It also includes strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality, and the implementation of the Healthy Start program and *Healthy People 2010* infant mortality objectives.

Agenda: The committee plans to discuss the following topics: The Healthy Start Program and its National Evaluation, Breastfeeding Rates, Maternal and Child Health Bureau's Depression Activities, and Centers for Medicare & Medicaid Services Program update. The meeting allots substantial time for subcommittee and full committee discussions to formulate the ACIM issues agenda. The items on the agenda items are subject to change as the Committee continues to discuss priorities.

The Committee provides a 5-minute time limit for each public comment. Submit comments no later than November 17, 2006.

For Further Information Contact: Anyone requiring information regarding the Committee can contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443-2170.