must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by January 8, 2009.

The agenda items are subject to change as priorities dictate.

Contact Person for More Information: Virginia S. Cain, PhD, Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7211, Hyattsville, Maryland 20782, telephone (301) 458–4500, fax (301) 458–4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 24, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–31340 Filed 1–2–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0642]

Draft Guidance for Industry and Food and Drug Administration Staff; Assay Migration Studies for In Vitro Diagnostic Devices; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Assay Migration Studies for In Vitro Diagnostic Devices.'' This draft guidance presents a least burdensome regulatory approach to gaining FDA approval of Class III or certain licensed in vitro diagnostic devices in cases when a previously approved assay is migrating (i.e., transitioning) to a New System for which the assay has not been previously approved or licensed.

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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 6, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Assay Migration Studies for In Vitro Diagnostic Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance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 or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 240–276–3151. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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.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–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0711.

For further information concerning the guidance including statistical content as it relates to devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852, 301–827–6210

For further information concerning the statistical content in the guidance: Marina V. Kondratovich, Center for Devices and Radiological Health (HFZ–550), Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850, 240–276–3126.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance presents a least burdensome regulatory approach to gain FDA's approval of Class III or certain licensed in vitro diagnostic devices, when a previously approved assay is migrating (i.e., transitioning) to a New System, for which the assay has not been previously approved or licensed. The regulatory approach in this guidance is also applicable to some 510(k) cleared devices, when the device transitioning to a new system presents specific concerns, either because of the nature of the analyte and indications, or because of the specific technology used (e.g., nucleic acid amplification tests). The focus of this guidance is on the study designs and performance criteria that should be fulfilled, so that sponsors can utilize the migration study approach in support of the change. The FDA believes that the assay migration study paradigm proposed in this draft guidance, provides a least burdensome scientific and regulatory pathway for manufacturers to transfer a previously approved or licensed assay, with full clinical data from an Old System to a New System (previously not approved or licensed). The paradigm is suitable in cases when sufficient knowledge can be derived from the documentation of design controls, risk analyses, and prior performance studies on an Old System.

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 assay migration studies for in vitro diagnostic devices. 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 ''Assay Migration Studies for In Vitro Diagnostic Devices,'' 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 1660 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.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 21 CFR part 807 subpart E have been approved under OMB Control Number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB Control Number 0910–0231; the collections of information in 21 CFR part 801 and 809 have been approved under OMB Control Number 0910–0485; the collections of information in 21 CFR 820 have been approved under OMB Control Number 0910–0073; and the collections of information in 21 CFR part 601 have been approved under OMB Control Number 0910–0338.

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–31319 Filed 1–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0437] (formerly Docket No. 2004D–0549)

Guidance for Industry on Labeling Over-the-Counter Human Drug Products—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products in complying with the agency's regulation on standardized content and format requirements for the labeling of OTC drug products. This guidance primarily discusses labeling questions that have been frequently asked by manufacturers, packers, and distributors relating to these requirements. The labeling examples in this guidance show various format and content features and suggest how OTC drug monograph labeling information finalized before the new requirements can be converted to the new format. This guidance finalizes the draft guidance of the same name published January 13, 2005 (70 FR 2415).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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: Gerald M. Rachanow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5496, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This is one of several guidances the agency has developed to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (§ 201.66 (21 CFR 201.66)). This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format requires revision of all prior labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug application, abbreviated new drug application, or OTC drug monograph (or drug product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquiries from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. To address these inquiries, FDA published a notice in the **Federal Register** of January 13, 2005 (70 FR 2415), announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' That draft guidance summarized the new Drug Facts labeling requirements as set forth in § 201.66. The draft guidance discussed those industry inquiries and