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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0347]

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Certifier A. Corbin

Draft Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff on In Vitro Diagnostic Multivariate Index Assays; Reopening of the Comment Period

72 FR 52885
9/17/07

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until *[insert date 30 days after date of publication in the Federal Register]*, the comment period for “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays” published in the **Federal Register** of July 26, 2007 (72 FR 41081). That guidance was a revised version of the original draft, which was published on September 7, 2006, with a 90-day comment period that was extended to 180 days. In addition, FDA held a public meeting on the draft guidance in February 2006. FDA is reopening the comment period on the revised draft to allow sufficient time for stakeholder comment.

DATES: Submit written or electronic comments by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Draft Guidance for industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays” to the Division of Small Manufacturers, International, and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
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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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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> or <http://www.regulations.gov>. 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, 240-276-0694.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 26, 2007 (72 FR 41081), FDA published a notice of availability of a revised draft guidance, "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays" with a 30-day comment period. The In Vitro Diagnostic Multivariate Index Assays (IVDMIA) guidance document has been the subject of attention, comment, and public discussion for almost a year. The original draft was published on September 7, 2006, with a 90-day comment period. In response to requests for further opportunity to comment, FDA extended the comment period to 180 days and held a public meeting on the guidance document. The second draft, which was published July 26, 2007,

incorporated many of the suggested comments on the first draft. Among other things, the second draft simplified the definition of IVDMIAs, and provided a variety of specific examples to assist sponsors in understanding the definition. In light of the opportunities for comment on the first draft, we had originally set a 30-day period for comments on the second draft. The initial comment period closed on August 27, 2007. However, at the request of in vitro diagnostic device stakeholders, the agency has decided to reopen the comment period for an additional 30 days 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 IVDMIAs.

II. Request for Comments

Following publication of the July 26, 2007, “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays,” FDA received requests to allow interested persons additional time to comment. The requesters asserted that the time period of 30 days was insufficient to respond fully to FDA’s specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. 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 IVDMIAs. 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.

IV. 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.

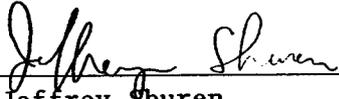
CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket 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>.

V. How to Submit 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: 9/11/2007
September 11, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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