4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0642]

# Assay Migration Studies for In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Assay Migration Studies for In Vitro Diagnostic Devices." This guidance presents a least burdensome regulatory approach to gain 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, licensed, or cleared.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Assay Migration Studies for In Vitro Diagnostic Devices" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. Alternatively, you may submit written requests for single copies of the guidance to the Office of Communication, Outreach and

Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 5524,

Silver Spring, MD 20993-002,

301-796-5455.

For further information concerning the study designs in the guidance:

Marina V. Kondratovich,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 5666,

Silver Spring, MD 20993-002,

301-796-6036.

For further information concerning the guidance as it relates to devices regulated by CBER:

Stephen Ripley,

Center for Biologics Evaluation and Research,

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852,

301-827-6210.

SUPPLEMENTARY INFORMATION:

## I. Background

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry and FDA staff entitled “Assay Migration Studies for In Vitro Diagnostic Devices.” This guidance presents a least burdensome regulatory approach to gain 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. The approach in this guidance is also applicable for some 510(k) cleared devices for which transition 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 in order for a sponsor to utilize the migration study approach in support of the change. The FDA believes that the assay migration study paradigm discussed in this 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.

The draft of this guidance was issued on January 5, 2009 (74 FR 302). The comment period closed on April 6, 2009. Three sets of comments were received and reviewed by FDA. The guidance was updated to address comments where appropriate. The updated guidance contains additional examples and explanations and supersedes the draft guidance "Assay Migration Studies for In Vitro Diagnostic Devices" issued on January 5, 2009.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "migration studies" for in vitro diagnostic device. 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.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. 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 301-847-8149 to receive a hard copy. Please use the document number 1660 to identify the guidance you are requesting. Guidance documents are also available on the CBER Internet site at

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.

## IV. Paperwork Reduction Act of 1995

This 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 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 either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

Dated: April 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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