4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0476]

Guidance for Industry and Food and Drug Administration Staff; Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices." This document describes FDA's intent with regard to enforcement of premarket notification (510(k)) requirements for certain in vitro diagnostic and radiology devices under the regulations.

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 "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology 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. 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:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA has identified certain Class I and Class II in vitro diagnostic and radiology devices that have established safety and effectiveness profiles and for which it believes 510(k) review is not necessary to assure safety and effectiveness. While FDA intends to exempt these devices from the 510(k) requirement through rulemaking that would reclassify the Class II devices and amend the classification regulations of the Class I devices, FDA no longer believes it is necessary to review premarket notification (510(k)) submissions for these devices before they enter the market. FDA is issuing a guidance concerning a policy of exercising enforcement

discretion with regard to the 510(k) requirement for such devices. The guidance lists the devices for which FDA intends to exercise enforcement discretion with regard to premarket notification requirements, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9. FDA intends to continue to enforce all other applicable requirements under the FD&C Act, including, but not limited to: Registration and listing (part 807 (21 CFR part 807)); labeling (part 801 (21 CFR part 801) and § 809.10 (21 CFR 809.10)); good manufacturing practice requirements as set forth in the Quality System regulation (part 820 (21 CFR part 820)); and Medical Device Reporting requirements (part 803 (21 CFR part 803)). The draft guidance published in the Federal Register on July 12, 2011 (76 FR 40921), and the comment period closed on October 11, 2011. There were 5 comments received.

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 "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology 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 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 "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic

and Radiology Devices," you may either send an email 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 1752 to identify the guidance you are requesting.

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 part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in part 807, subparts B and C have been approved under OMB control number 0910-0387; the collections of information in part 820 have been approved under OMB control number 0910-0073; the collections of information in part 801 and § 809.10 have been approved under OMB control number 0910-0485; and the collections of information in part 803 have been approved under OMB control number 0910-0437.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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