4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0300] (formerly Docket No. 2006D-0504)

Radio Frequency Wireless Technology in Medical 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 "Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff." This guidance document is intended to assist industry and FDA staff in identifying and appropriately addressing specific considerations related to the incorporation and integration of radio frequency (RF) wireless technology in medical devices. This guidance discusses issues that may affect the safe and effective use of medical devices that incorporate RF wireless technology, including selection of wireless technology, quality of service, coexistence, security, and electromagnetic compatibility, and provides recommendations for information to be included in FDA premarket submissions for such devices.

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 "Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff" to the Division of Small Manufacturers, International and

Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach, and Development (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 those offices in processing your request, or fax your request to CDRH at 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: Donald Witters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1130, Silver Spring, MD 20993-0002, 301-796–2483; or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this guidance document to assist industry, systems and service providers, consultants, FDA staff, and others involved in the design, development, and evaluation of RF wireless technology in medical devices. The use and deployment of RF wireless technology in and around medical devices is an increasing concern because the electromagnetic environments

where medical devices are used might contain many sources of RF energy, and the RF wireless emissions from one product or device could potentially affect the function of another. The guidance recommends that manufacturers address the potential issues that relate to the incorporation of RF wireless technology that may affect the safe and effective use of medical devices.

The draft guidance document and comment period were announced in the Federal Register on January 3, 2007 (72 FR 137). The comment period closed on April 2, 2007. Over 25 companies, numerous organizations, and many individuals provided around 180 comments. FDA considered all of the comments and revised the guidance where appropriate.

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 radio frequency wireless technology in medical 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 or the CBER Internet site at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. To receive "Radio Frequency Wireless Technology in Medical Devices;

Guidance for Industry and Food and Drug Administration Staff," 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 1618 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. 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 801 have been approved under OMB control number 0910-0485; 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 814, subpart H have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

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: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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