4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0798]

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices; Mobile Medical Applications: Guidances 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 two guidance documents. FDA is issuing "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with regulatory requirements for Medical Device Data Systems (MDDS) and two similar radiology device types due to the low risk they pose to patients and the importance they play in advancing digital health. FDA is also issuing an updated version of the guidance document "Mobile Medical Applications," originally issued on September 25, 2013, that has been edited to be consistent with the MDDS guidance document.

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: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document

entitled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" or the updated version of "Mobile Medical Applications" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Alternatively, you may submit written requests for single copies of the guidances to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidances 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 on "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" with the docket number found in brackets in the heading of this document. Identify comments on "Mobile Medical Applications" with the docket number FDA-2011-D-0530.

FOR FURTHER INFORMATION CONTACT: For devices regulated by CDRH: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5456, Silver Spring, MD 20993-0002, 301-796-5528. For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that the progression to digital health offers potential for better, more efficient patient care and improved health outcomes. To achieve this goal requires that many medical devices be interoperable with various types of health information technology, including other types of medical devices. The foundation for such intercommunication is hardware and software that functions to transfer, store, convert formats, or display medical device data without modifying the data or controlling the functions or parameters of any connected medical device.[1] In the Federal Register of February 15, 2011 (76 FR 8637), FDA issued a final rule defining MDDS devices, medical image storage devices, and medical image communications devices, reclassifying them from class III (high risk) to class I (low risk). Class I devices are subject to general controls under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Since issuance of the February 2011 final rule, FDA has gained additional experience with these types of technologies and has determined that these devices pose a low risk to the public. Therefore, in the documents that are the subject of this notice, FDA provides guidance on the compliance policy for MDDS devices, medical image storage devices, and medical image communication devices and makes conforming changes to the guidance document "Mobile Medical Applications." FDA issued a notice of availability of the draft guidances on June 25, 2014 (79 FR 36072).

The guidance document, "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices," states that FDA does not intend to enforce compliance with the regulatory requirements that apply to MDDS devices, medical image storage devices, and medical image communications devices. Blood Establishment

[1] MDDS are not intended to be used for active patient monitoring.

Computer Software (BECS) and accessories to BECS are not MDDS devices. Therefore, this guidance does not address the regulation of those devices, which FDA intends to address in another forum. If you have questions about BECS or BECS accessories, please contact the Office of Communication Outreach and Development, CBER at 800-835-4709, 240-402-7800, or email ocod@fda.hhs.gov.

The September 25, 2013, version of the guidance entitled "Mobile Medical Applications" has been updated to be consistent with the policy stated in the guidance document "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices." The updated version of "Mobile Medical Applications" also incorporates additional examples from FDA's mobile medical applications' Web site (see http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm).

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 medical device data systems, medical image storage devices, and medical image communications devices as well as mobile medical applications. 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 guidances may do so by downloading an electronic copy from 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 from CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. Persons unable to download an electronic copy of "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" or "Mobile Medical Applications" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400001 to identify the guidance "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" or document number 1741 to identify the guidance "Mobile Medical Applications."

IV. Paperwork Reduction Act of 1995

The guidance documents "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" and "Mobile Medical Applications" refer to previously approved information collections found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Review Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 and 809 are approved under OMB control number 0910-0485; the collections of information in 21 CFR part 803 are approved under OMB control numbers 0910-0437 and 0910-0291; the collections of information in 21 CFR part 806 are approved under OMB control number 0910-0359; the collections of information in 21 CFR part 807 subparts B and C are approved under OMB control number 0910-0625; the collections of information in 21 CFR part 807 subpart E are approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; the

collections of information in 21 CFR part 814 subparts A through E are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073; and the collections of information regarding section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) are approved under OMB control number 0910-0705.

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: February 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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