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Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices." FDA is issuing this document to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with the regulatory controls that apply to Medical Device Data Systems (MDDS), medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they play in advancing digital health. In this document, FDA is also proposing changes to its guidance entitled "Mobile Medical Applications," issued on September 25, 2013, to conform to the proposed policy discussed in this draft guidance document. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 Submit written requests for a single hard copy of the draft guidance document entitled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" to the Office of the Center Director,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. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that the progression to digital health offers the 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 inter-communication is hardware and

software that transfer, store, convert formats, and display medical device data. FDA has called such technologies MDDS. A MDDS does not modify the data, and it does not control the functions or parameters of any connected medical device. MDDS are not intended to be used for active patient monitoring.

On February 15, 2011 (76 FR 8637), FDA issued a regulation down-classifying MDDS 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. Since then, FDA has gained additional experience with these types of technologies and has determined that these devices pose a low risk to the public. Therefore, this document proposes a compliance policy whereby FDA would not intend to enforce compliance with the regulatory controls that apply to MDDS devices, medical image storage devices, and medical image communications devices.

This document also proposes changes to the Agency's 2013 guidance entitled "Mobile Medical Applications" which would conform to the policy stated in this document, once this document is finalized. Upon finalization, the description of these conforming changes will be removed from this document and FDA will issue an updated version of the "Mobile Medical Applications" guidance that incorporates these changes.

II. 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 medical device data systems, medical image storage devices, and medical image communications 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 draft guidance 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. Persons unable to download an electronic copy of "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400021 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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: June 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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