4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0530]

Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Mobile Medical Applications." FDA is issuing this draft guidance to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or "mobile apps"). At this time, FDA intends to apply its regulatory requirements solely to a subset of mobile apps that the Agency is calling mobile medical applications (mobile medical apps). This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Mobile Medical Applications" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and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 to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. 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Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

For devices regulated by CDRH:

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Food and Drug Administration,

10903 New Hampshire Ave.,

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Silver Spring, MD 20993-0002,

301-796-5528.

For devices regulated by CBER:

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

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I. Background

Given the rapid expansion and broad applicability of mobile apps, FDA is issuing this draft guidance to clarify the types of mobile apps to which FDA intends to apply its authority. At this time, FDA intends to apply its regulatory requirements to a subset of mobile apps that the Agency is calling mobile medical apps. For purposes of this guidance, a "mobile medical app" is defined as a mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321)[1]; and either:

- is used as an accessory to a regulated medical device or
- transforms a mobile platform into a regulated medical device.

This narrowly-tailored approach focuses on a subset of mobile apps that either have traditionally been considered medical devices or affect the performance or functionality of a currently regulated medical device.

[1] Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as "* * *an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent * * *," that is "* * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man* * *" or "* * * intended to affect the structure or any function of the body of man or other animals* * *."

Although some mobile apps that do not meet the definition of mobile medical app may meet the FD&C Act's definition of a device, the FDA intends to exercise enforcement discretion[2] towards those mobile apps.

We welcome comments on all aspects of this guidance as well as the following specific issues:

1. FDA generally considers extensions of medical devices as accessories to those medical devices. Accessories have been typically regulated under the same classification as the connected medical device. However, we recognize potential limitations to this policy for mobile medical apps. FDA seeks comments on how the Agency should approach accessories and particularly mobile medical apps that are accessories to other medical devices so safety and effectiveness can be reasonably assured. For example, one possible approach could be the following:

• An accessory that does not change the intended use of the connected device, but aids in the use of the connected medical device could be regulated as class I. For example, such an accessory would be similar to an infusion pump stand, which is currently classified as a class I device because it supports the intended use of an infusion pump (class II medical device). A mobile medical app that simply supports the intended use of a regulated medical device could be classified as class I with design controls as part of the quality systems requirements.

• An accessory that extends the intended use of the connected medical device could be classified with the connected device. For example, if a mobile medical app that performs more detailed analysis than the connected medical device while maintaining the original intended use,

[2] This means that FDA intends to exercise its discretion to decline to pursue enforcement actions for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile medical app, as specified in this guidance. This does not constitute a change in the requirements of the FD&C Act or any applicable regulations.

which is data analysis, could be classified in the same classification as the connected medical device.

• An accessory that creates a new intended use from that of the connected device(s) could be classified according to the risk posed to patient safety by the new intended use, for example, if the intended use of a mobile medical app is to provide prognosis relating to a certain disease or condition and the mobile medical app is connected to a device that does not have that intended use, the mobile medical app may have a different level of risk than the connected device, resulting in a different classification to assure of safety and effectiveness of the mobile medical app.

2. FDA has not addressed in this guidance stand-alone software (mobile or traditional workstation) that analyzes, processes, or interprets medical device data (collected electronically or through manual entry of the device data) for purposes of automatically assessing patient specific data or for providing support in making clinical decisions. FDA plans to address such stand-alone software in a separate guidance. In order to provide a reasonable assurance of the safety and effectiveness of such software, and to ensure consistency between this guidance and the planned guidance on stand-alone software that provides clinical decision support (CDS), FDA is seeking comments on the following issues:

• What factors should FDA consider in determining the risk classification of different types of software that provide CDS functionality? Please provide examples of how those factors would be applied for such software that you believe should be in class I, class II, and class III.

• How should FDA assess stand-alone software that provides CDS functionality, to assure reasonable safety and effectiveness? For example, to what extent can FDA rely on a manufacturer’s demonstration that it has a robust quality system with appropriate quality

assurance and design controls? Under what circumstances should the submission of clinical data be required?

• Are there specific controls that manufacturers should implement that could change the risk classification or reduce the premarket data requirements for particular types of stand-alone software that provide CDS functionality?

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 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 draft 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 either http://www.regulations.gov or http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive "Mobile Medical Applications" from CDRH, 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 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 are approved under OMB control number 0910-0485; the collection of information in 21 CFR part 803 are approved under OMB control number 0910-0437; 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, subpart B, are approved under OMB control number 0910-0387; the collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073.

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: .July 18, 2011.

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Deputy Director for Policy,

Center for Devices and Radiological Health.

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