

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Mobile Medical Applications; 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 "Mobile Medical Applications." The FDA is issuing this 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, the FDA intends to apply regulatory requirements to only a small subset of mobile apps referred to in this guidance as mobile medical applications (mobile medical apps).

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 "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, suite 200N, 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 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: 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 (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

## I. Background

Given the rapid expansion and broad applicability of mobile apps, the FDA is issuing this guidance document to clarify the subset of mobile apps to which the FDA intends to apply its authority. Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them. Some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise

enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act). The majority of mobile apps on the market at this time fit into these two categories.

Consistent with the FDA's existing oversight approach that considers functionality rather than platform, the FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps.

FDA is issuing this guidance to provide clarity and predictability for manufacturers of mobile medical apps. Should FDA determine at a later date that the policy in this guidance should be changed in light of new information, the agency would follow a public process, including the opportunity for public input, consistent with FDA's good guidance practices (GGP) regulation in 21 CFR 10.115.

In the Federal Register of July 21, 2011 (76 FR 43689), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 19, 2011. FDA reviewed the comments and revised the guidance, as 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 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 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

<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](mailto: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 guidance refers 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 Reduction Act of 1995 (44 U.S.C. 3501-3520). 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; the collections of information in 21 CFR part 814 Subparts B and E are approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 820 are 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: September 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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