4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0339]

Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology Report; Notice to Public of Availability of the Report and Web Site Location; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the report and Web site location where the Agency has posted the report entitled "Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework." In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on this document 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, 301-796-5528, Bakul.patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) became law on July 9, 2012. Section 618 of FDASIA requires that FDA, in consultation with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communication Commission (FCC), develop and post on their respective Web sites "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology (IT), including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." This "FDASIA Health IT Report: Proposed Risk Based Regulatory Framework" report fulfills that requirement.

This notice announces the availability and Web site location of "FDASIA Health IT Report: Proposed Risk Based Regulatory Framework." FDA, ONC, and FCC invite interested persons to submit comments on this report. We have established a docket where comments may be submitted (see ADDRESSES). We believe this docket is an important tool for receiving feedback on this report from interested parties and for sharing this information with the public. To access "FDASIA Health IT Report: Proposed Risk Based Regulatory Framework," visit FDA's Web site http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm390588.htm or ONC's Web site, www.healthit.gov/FDASIA.

II. Request for 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: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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