TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
600.12[2]	164	41.99	6,887	32	220,384
600.12(b)(2)	334	5.03	1,679	24	40,296
600.80(c)(1) and 600.80(i)	131	1,718.60	225,137	1	225,137
Total					485,817

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07711 Filed 4–4–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0341]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's ''Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' The guidance describes procedures and responsibilities for updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and also describes procedures for making corresponding changes to susceptibility test interpretive criteria for antimicrobial susceptibility testing devices.

DATES: Submit either electronic or written comments on the collection of information by June 6, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices—(OMB Control Number 0910–0638)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. As a result of this provision, the guidance explains the importance of making available to health care providers the most current information regarding susceptibility test interpretive criteria for antibacterial drug products. To address concerns about antibacterial drug product labeling with out-of-date information on susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods, the guidance describes procedures for FDA, applications holders, and antimicrobial susceptibility testing device manufacturers to ensure that updated susceptibility test information is available to health care providers. Where appropriate, FDA will identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. FDA recognized standards will be available to application holders of approved

antibacterial drug products for updating their product labeling.

Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: Submit a labeling supplement that relies upon a standard recognized by FDA in a **Federal Register** notice or submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the ''Microbiology'' subsection of their product labeling is current or whether changes are needed. This information collection is already approved by OMB under control number 0910–0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and control number 0910–0001 (the requirement in 21 CFR 314.70(b)(2)(v) to submit labeling supplements for certain changes in the product's labeling and the requirement in 21 CFR 314.81(b)(2)(i) to include in the annual report a brief summary of significant new information from the previous year that might affect the labeling of the drug product).

In addition, under the guidance, if the information in the applicant's product labeling differs from the standards recognized by FDA in the **Federal Register** notice, and the applicant believes that changes to the labeling are not needed, the applicant should provide written justification to FDA why the recognized standard does not apply to its drug product and why changes are not needed to the ''Microbiology'' subsection of the product's labeling. This justification should be submitted as general correspondence to the product's application, and a statement indicating that no change is currently needed and the supporting justification should be included in the annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and our experience with the FDAAA requirement and the guidance recommendations during the past 16 months, we estimate that, annually, approximately two applicants will submit the written justification described previously and in the guidance, and that each justification will take approximately 16 hours to prepare and submit to FDA as general correspondence and as part of the annual report.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Justification Submitted as General Correspondence and in the Annual Report	2	1	2	16	32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07704 Filed 4–4–14; 8:45 am]

BILLING CODE 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 July 7, 2014.

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