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

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.

[FR Doc. 2014–07658 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–2012–E–0490]

Determination of Regulatory Review Period for Purposes of Patent Extension; MELAFIND SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MELAFIND SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device MELAFIND SYSTEM. MELAFIND SYSTEM is indicated for use on clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MELAFIND SYSTEM (U.S. Patent No. 6,208,749) from MELA Sciences Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 10, 2012, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of MELAFIND SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MELAFIND SYSTEM is 3,837 days. Of this time, 2,961 days occurred during the testing phase of the regulatory review period, while 876 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective, or, if an investigational device exemption (IDE) was not required, but institutional review board (IRB) approval is required, under section 520(g)(3) of the FD&C Act, the IRB approval date:* May 2, 2001. The applicant claims there was no IDE submitted under section 520(g) of the FD&C Act and claims the date that IRB-required approval was effective was May 2, 2001. FDA concurs that no IDE was submitted and that the IRB approval action was enacted May 2, 2001, according to the certificate of approval substantiating IRB approval date provided in the application for patent term extension.

2. *The date an application was initially submitted with respect to the device under section 515 of the the FD&C Act (21 U.S.C. 360e):* June 9, 2009. FDA has verified the applicant's claim that the premarket approval application (PMA) for MELAFIND SYSTEM (PMA P090012) was initially submitted June 9, 2009.

3. *The date the application was approved:* November 1, 2011. FDA has verified the applicant's claim that PMA P090012 was approved on November 1, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2,355 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 6, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 6, 2014. To meet its burden, the petition must contain sufficient facts to