approved under OMB control number 0910–0756.

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: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08364 Filed 4–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0475]

Determination of Regulatory Review Period for Purposes of Patent Extension; ELVITEGRAVIR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ELVITEGRAVIR (as a component of STRIBILD) 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

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, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product ELVITEGRAVIR (as a component of STRIBILD (cobicistat/emtricitabine/ELVITEGRAVIR/tenofovir disoproxil fumarate)). STRIBILD is indicated as a complete regimen for the treatment of HIV–1 infection in adults who are antiretroviral treatment-naive. Subsequent to this approval, the USPTO received a patent term restoration application for ELVITEGRAVIR (as a component of STRIBILD) (U.S. Patent No. 7,176,220) from Japan Tobacco Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2013, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of STRIBILD represented the first permitted commercial marketing or use of the ELVITEGRAVIR product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ELVITEGRAVIR (as a component of STRIBILD) is 2,666 days. Of this time, 2,360 days occurred during the testing phase of the regulatory review period, while 306 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* May 12, 2005. The applicant claims May 18, 2005, as the date the investigational new drug application (IND) for ELVITEGRAVIR became effective. However, FDA records indicate that the IND effective date was May 12, 2005, which was the date the IND sponsor was notified that clinical trials may proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 27, 2011. The applicant claims October 26, 2011, as the date the new drug application (NDA) for STRIBILD (NDA 203–100) was initially submitted. However, FDA records indicate that NDA 203–100 was submitted on October 27, 2011.

3. *The date the application was approved:* August 27, 2012. FDA has verified the applicant's claim that NDA 203–100 was approved on August 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,021 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 12, 2015. 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 13, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic

petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08362 Filed 4–10–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0090]

Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval; 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 ''Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval.'' This guidance clarifies FDA's current policy on balancing premarket and postmarket data collection during the Agency's review of premarket approval applications (PMA). Specifically, this guidance outlines how FDA considers the role of postmarket information in determining the appropriate type and amount of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of safety and effectiveness. FDA believes this guidance will improve patient access to safe and effective medical devices that are important to public health by improving the predictability, consistency, transparency, and efficiency of the premarket process.

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: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

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: Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5449, Silver Spring, MD 20993–0002, 301–796–5178; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long applied postmarket controls as a way to reduce premarket data collection, where appropriate, while assuring that the statutory standard for approval of reasonable assurance of safety and effectiveness is still met. The right balance of premarket and postmarket data collection facilitates timely patient access to important new technology without undermining patient safety.

In this guidance, FDA describes existing statutory requirements under the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and FDA policies that support the policy on balancing premarket and postmarket data collection during review of PMAs. In addition, FDA clarifies how the Agency considers postmarket data as part of the benefit-risk framework described in FDA's guidance ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications,'' issued on March 28, 2012. This guidance provides a resource for industry and FDA staff on how FDA determines when it is appropriate for a sponsor of a PMA to collect some data (clinical or non-clinical) in the postmarket setting, rather than premarket.

A draft of this guidance was made available in the **Federal Register** on April 23, 2014, and the comment period closed July 22, 2014. Changes between the draft and final versions of this guidance include an increased focus on patient outcomes and additional examples to help industry better understand when it may be appropriate to shift data collection from the premarket to postmarket setting. The final guidance also recognizes the potential for use of registry data to satisfy post-approval study requirements.

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 balancing premarket and postmarket data collection for devices subject to premarket approval. 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 downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health 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 from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1833 to