In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. Members of the ICH Steering Committee include the European Union; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; Swissmedic; and the World Health Organization (as an Observer). The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

II. Meeting Attendance and Participation

A. Registration

If you wish to attend the meeting, visit *https://www.eventbrite.com/e/international-conference-on-harmonization-regional-public-meeting-tickets-16183519342.* Please register for the meeting by May 11, 2015. Seating may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meetings will be based on space availability.

If you need special accommodations because of a disability, please contact Tracy Porter (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 3:30 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Tracy Porter (see **FOR FURTHER INFORMATION CONTACT**) by May 11, 2015, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm439475.htm.*

III. Comments

Interested persons may submit either electronic or written comments to the public docket (see **ADDRESSES**) by June 14, 2015. 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.*

IV. Transcripts

Please be advised that as soon as a meeting transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm439475.htm.*

Dated: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08359 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–2014–D–0363]

Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions; 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 or the Agency) is announcing the availability of the guidance entitled ''Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions.'' This guidance outlines FDA's new, voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions and that are subject to premarket approval (PMA) applications or de novo classifications. FDA believes that the Expedited Access Pathway (EAP) program will help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval, consistent with the Agency's mission to protect and promote public health. The document also discusses how the EAP program approaches the balance of premarket and postmarket data collection and incorporates a benefit-risk framework. The EAP program will become effective April 15, 2015.

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 ''Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or

Irreversibly Debilitating Diseases or Conditions'' 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's EAP program contains features from the Center for Devices and Radiological Health's (CDRH's) Innovation Pathway, piloted in 2011 to facilitate the development and expedite the review of breakthrough technologies. In addition, the EAP program is based in part on FDA's experience with the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions (''FDA drug-expedited programs''). However, while the EAP program incorporates some features of the FDA drug-expedited programs, it is a separate and distinct program tailored to devices and intended to further speed the availability of certain safe and effective devices that address unmet public health needs.

As part of the EAP program, FDA intends to provide more interactive communications during device development and more interactive review of Investigational Device Exemption applications, PMA applications, and requests for de novo review. This includes working with the sponsor to create a data development plan specific to the device, which would outline all data the sponsor intends to collect in support of device approval, and identifying what data would be collected premarket and postmarket. In addition, FDA intends to work interactively with the sponsor within the benefit-risk framework discussed in the FDA guidance, ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications,'' issued on March 28, 2012, and in accordance with statutory and regulatory requirements, to determine whether certain data may be collected in the postmarket setting rather than in the premarket setting for devices subject to PMAs. This guidance details the EAP process, which will only be utilized at the request of the sponsor and with FDA's agreement.

At the time of this document's publication, FDA does not know whether the EAP program will require a significant increase in resources. FDA will devote as many resources to EAP as possible without adversely impacting our ability to meet our Medical Device User Fee Act commitments. Our experience with the Innovation Pathway showed that early and more extensive interactions with sponsors can consume a significant amount of manager and staff time. FDA plans to closely monitor implementation of EAP to determine whether we have sufficient resources to effectively implement the program.

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 expanding the scope to include de novo requests, an increased focus on patient benefits, a clarification of how FDA will allocate resources to the EAP program, and a clarified explanation of the EAP designation process. FDA also provided more examples to help industry better understand in which cases EAP may be the most appropriate pathway to device approval. The final guidance also recognizes the potential for use of registry data to satisfy post-approval study requirements and adds an evaluation mechanism for the EAP program.

The EAP program will become effective April 15, 2015.

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 the Expedited Access PMA program. 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 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 from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400007 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449; and the collections of information regarding ''Requests for Feedback on Medical Device Submissions'' have been

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