Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 MEKINIST (trametinib dimethyl sulfoxide solvate). MEKINIST is indicated for treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutations as detected by an FDA-approved test. Subsequent to this approval, the USPTO received a patent term restoration application for MEKINIST (U.S. Patent No. 7,378,423) 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 May 11, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of MEKINIST represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MEKINIST is 1,842 days. Of this time, 1,542 days occurred during the testing phase of the regulatory review period, while 300 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 15, 2008. FDA has verified the Japan Tobacco, Inc., claim that May 15, 2008, is the date the investigational new drug application became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 3, 2012. The applicant claims August 2, 2012, as the date the new drug application (NDA) for MEKINIST (NDA 204–114) was initially submitted. However, FDA records indicate that NDA 204–114 was submitted on August 3, 2012.

3. *The date the application was approved:* May 29, 2013. FDA has verified the applicant's claim that NDA 204–114 was approved on May 29, 2013.

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 623 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

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

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12859 Filed 5–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–0861]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OTEZLA 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.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 1, 2016. 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 November 28, 2016. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–E–0861 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; OTEZLA.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 OTEZLA (apremilast). OTEZLA is indicated for treatment of adult patients with active psoriatic arthritis. Subsequent to this approval, the USPTO received a patent term restoration application for OTEZLA (U.S. Patent No. 7,427,638) from Celgene Corporation, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OTEZLA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OTEZLA is 3,494 days. Of this time, 3,128 days occurred during the testing phase of the regulatory review period, while 366 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:* August 28, 2004. FDA has verified the Celgene Corporation claim that August 28, 2004, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 21, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for OTEZLA (NDA 205437) was initially submitted on March 21, 2013.

3. *The date the application was approved:* March 21, 2014. FDA has verified the applicant's claim that NDA 205437 was approved on March 21, 2014.

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 1,186 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

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

Dated: May 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12829 Filed 5–31–16; 8:45 am]

BILLING CODE 4161–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

OpenFDA Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: OpenFDA Public Workshop. The purpose of the public workshop is to provide a forum for the openFDA system user community to engage in a robust interactive discussion and provide feedback to FDA regarding openFDA's platform, application programming interfaces (APIs), downloadable harmonized datasets, and possible enhancements to the openFDA platform, as well as to view the demonstration of various applications (apps) specifically developed for utilization of openFDA data.

DATES: The public workshop will be held on June 20, 2016, from 9 a.m. to 12 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Building 31 (The Great Room 1503A), Silver Spring, MD 20993. For information regarding ground transportation, airports, lodging, driving, and parking, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Lonnie Smith, Office of Health Informatics, Office of Chief Scientist, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8503, email: *lonnie.smith@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: OpenFDA, an FDA Office of Health Informatics initiative launched in June 2014, is making it easier for researchers, scientists, web developers, and other FDA regulatory stakeholders to access and use datasets in an open standard format.

The project aims to create easy access to public data and a new level of openness and accountability, ensure the privacy and security of public FDA data, educate the public, and save lives.

Members of the scientific community can use openFDA to have their applications automatically query the data through APIs. OpenFDA increases the efficiency and speed of accessing datasets by using cutting-edge, open-source code modules in a cloud-based environment.

Requests for openFDA app demonstrations: This public workshop includes demonstrations of mobile apps specifically developed for utilization of openFDA data. During registration you may indicate if you wish to provide a demonstration of an app which you have created that utilizes openFDA data. FDA will do its best to accommodate requests to demonstrate openFDA-based apps. The openFDA app demonstrations should not include any presentation slides and, due to FDA internet firewall restrictions, will be limited to only information and displays accessible via apps which can be accessed via internet browsers Internet Explorer version 11 and Firefox versions 6 or higher. All requests to make app demonstrations must be received by 5 p.m., June 6, 2016. FDA will determine the amount of time allotted to each presenter and the approximate time each app demonstration is to begin, and will select and notify participants by 5 p.m., June 10, 2016. If selected for an app demonstration, any demonstration materials must be emailed to Lonnie Smith (see **FOR FURTHER INFORMATION CONTACT**) no later than 5 p.m., June 16, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Registration: There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this workshop must register by sending the attendee's full name and email address via email message to *openFDA@fda.hhs.gov* before June 10, 2016. For those without Internet access, please contact Lonnie Smith (see **FOR FURTHER INFORMATION CONTACT**) to register.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register by 4 p.m., June 10, 2016. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after June 10, 2016.

If you need special accommodations due to a disability, please contact Lonnie Smith (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12826 Filed 5–31–16; 8:45 am]

BILLING CODE 4164–01–P