

## II. Topics for Discussion at the Public Meeting

As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (FDARA), this FDA meeting on the development and labeling of pediatric medical devices is being convened with representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007, medical provider organizations, and organizations representing patients and consumers (see Pub. L. 110–85; 42 U.S.C. 282 note).

As directly outlined in FDARA, the meeting shall include consideration of ways to: (1) Improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for pediatric populations that would result in the approval or clearance, and labeling of medical devices for such populations; (2) appropriately use extrapolation under section 515A(b) of the FD&C Act (21 U.S.C. 360e–1(b)); (3) enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling; (4) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use; and (5) identify current barriers to pediatric device development and incentives to address such barriers.

A detailed agenda will be posted on the following website in advance of the workshop at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. Select this event from the list of items provided.

## III. Participating in the Public Meeting

**Registration:** To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free, and in-person attendance is based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by August 6, 2018, 3 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the

number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Peggy Roney at the Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5671, [Peggy.Roney@fda.hhs.gov](mailto:Peggy.Roney@fda.hhs.gov), no later than June 1, 2018.

**Requests for Oral Presentations:** During online registration, you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. We encourage persons who are interested in making an oral presentation during a public comment session to indicate their intent on the registration form by 3 p.m. Eastern Time on June 29, 2018. Based on the number of applicants for oral presentations, FDA will distribute the available time equally among all presenters and inform selected presenters of the public presentation agenda by July 6, 2018. If selected for presentation, any presentation materials must be emailed to Victoria Wagman at [Victoria.wagman@fda.hhs.gov](mailto:Victoria.wagman@fda.hhs.gov) no later than July 13, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

**Streaming Webcast of the public meeting:** This public meeting will also be webcast. The webcast link will be available on the registration web page after August 6, 2018. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (<https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>) and select this event from the list of items provided. Organizations are requested to register all participants but view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit <https://www.adobe.com/>

[go/connectpro\\_overview](https://www.fda.gov/oc/connectpro_overview). FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

## IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. FDA's guidance for Industry and FDA Staff: "Pre-market Assessment of Pediatric Medical Devices," available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf>.

2. FDA's guidance for Industry and FDA Staff: "Providing Information about Pediatric Uses of Medical Devices," available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339465.pdf>.

3. FDA's guidance for Industry and FDA Staff: "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices," available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm444591.pdf>.

Dated: February 12, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–03215 Filed 2–15–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA–2016–E–2512 and FDA–2016–E–2511]

### Determination of Regulatory Review Period for Purposes of Patent Extension; COTELLIC

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has

determined the regulatory review period for COTELLIC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 17, 2018. 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 August 15, 2018. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 17, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 17, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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 Nos. FDA-2016-E-2512 and FDA-2016-E-2511 for "Determination of Regulatory Review Period for Purposes of Patent Extension; COTELLIC." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: <https://www.gpo.gov/>

<https://www.regulations.gov/pdfs/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 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 COTELLIC (cobimetinib). COTELLIC is indicated for treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation,

in combination with vemurafenib. Subsequent to this approval, the USPTO received patent term restoration applications for COTELLIC (U.S. Patent Nos. 7,803,839 and 8,362,002) from Exelixis, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 26, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of COTELLIC 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 COTELLIC is 3,219 days. Of this time, 2,884 days occurred during the testing phase of the regulatory review period, while 335 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* January 19, 2007. FDA has verified the Exelixis, Inc. claim that January 19, 2007, 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 of the FD&C Act:* December 11, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for COTELLIC (NDA 206192) was initially submitted on December 11, 2014.

3. *The date the application was approved:* November 10, 2015. FDA has verified the applicant's claim that NDA 206192 was approved on November 10, 2015.

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 applications for patent extension, this applicant seeks 1,013 days or 676 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, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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 <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 12, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–03218 Filed 2–15–18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–D–1540]

#### **Migraine: Developing Drugs for Acute Treatment; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Migraine: Developing Drugs for Acute Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of prescription drugs for the acute treatment of migraine. This guidance focuses on specific drug development and trial design issues that are unique to the study of prescription drugs for the acute treatment of migraine. This guidance finalizes the draft guidance of the same name issued October 22, 2014.

**DATES:** The announcement of the guidance is published in the **Federal Register** on February 16, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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–2014–D–1540 for “Migraine: Developing Drugs for Acute Treatment; Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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