

information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/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 numbers, 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 ZURAMPIC (lesinurad). ZURAMPIC is indicated in combination with a xanthine oxidase inhibitor for the treatment of

hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. Subsequent to this approval, the USPTO received patent term restoration applications for ZURAMPIC (U.S. Patent Nos. 8,003,681; 8,084,483; 8,283,369; 8,357,713; and 8,546,437) from Ardea Biosciences, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated November 10, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZURAMPIC 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 ZURAMPIC is 2,245 days. Of this time, 1,886 days occurred during the testing phase of the regulatory review period, while 359 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:* October 31, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 31, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 29, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for ZURAMPIC (NDA 207988) was initially submitted on December 29, 2014.

3. *The date the application was approved:* December 22, 2015. FDA has verified the applicant's claim that NDA 207988 was approved on December 22, 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 971 days, 127 days, 391 days, and 237 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: January 16, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-00992 Filed 1-19-18; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket Nos. FDA-2016-E-2463; FDA-2016-E-2464; FDA-2016-E-2465; and FDA-2016-E-2466]

### **Determination of Regulatory Review Period for Purposes of Patent Extension; NINLARO**

**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 NINLARO 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 March 23, 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 July 23, 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 March 23, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 23, 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-2463; FDA-2016-E-2464; FDA-2016-E-2465; and FDA-2016-E-2466 for "Determination of Regulatory Review Period for Purposes of Patent Extension; NINLARO." 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 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 "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/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

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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 NINLARO (ixazomib). NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Subsequent to this approval, the USPTO received patent term restoration applications for NINLARO (U.S. Patent Nos. 7,442,830; 7,687,662; 8,003,819; and 8,859,504) from Millennium Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 14, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of

NINLARO 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 NINLARO is 2,538 days. Of this time, 2,404 days occurred during the testing phase of the regulatory review period, while 134 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:* December 10, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 10, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 10, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for NINLARO (NDA 208462) was initially submitted on July 10, 2015.

3. *The date the application was approved:* November 20, 2015. FDA has verified the applicant's claim that NDA 208462 was approved on November 20, 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 837 or 157 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: January 16, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–00994 Filed 1–19–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Service Administration

#### Advisory Committee on Heritable Disorders in Newborns and Children

**AGENCY:** Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

**DATES:** Thursday, February 8, 2018, from 9:30 a.m. to 5:00 p.m. and Friday, February 9, 2018, from 9:30 a.m. to 3:00 p.m. ET (meeting times are tentative).

**ADDRESSES:** The address for the meeting is 5600 Fishers Lane, 5th Floor Pavilion, Rockville, MD 20857. Participants may also access the meeting through Webcast. Advanced registration is required. Please register online at <http://www.achdncmeetings.org/> by 12:00 p.m. ET on February 5, 2018. Instructions on how to access the meeting via Webcast will be provided upon registration.

Please note that the 5600 Fishers Lane building requires security screening on entry. Visitors must provide a driver's license, passport, or other form of government-issued photo identification or they cannot enter the facility. Non-US Citizens planning to attend in person will need to provide additional information to HRSA by January 24, 2018, 12:00 p.m. Eastern Time. Please see contact information below.

#### FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the ACHDNC should contact Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three

ways: (1) Send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; (2) call 301–443–3999; or (3) send an email to: [AFerrero@hrsa.gov](mailto:AFerrero@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The ACHDNC provides advice to the Secretary of HHS on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC's recommendations regarding inclusion of additional conditions and inherited disorders for screening which have been adopted by the Secretary are then included in the Recommended Uniform Screening Panel (RUSP). Conditions listed on the RUSP constitute part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13. Under this provision, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening. Information about the ACHDNC is available on the following website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

The meeting agenda will include a final evidence-based review report on the spinal muscular atrophy (SMA) condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend to the Secretary adding SMA to the RUSP. ACHDNC members will also hear presentations on states' activities to achieve newborn screening timeliness goals. An overview of cutoff determinations and risk assessment methods used for dried bloodspot newborn screening will also be given. The Committee expects to vote on whether to support a guidance document on cutoff determinations and risk assessment methods. Finally, the ACHDNC members will hear updates from the Laboratory Standards and Procedures workgroup; the Follow-up and Treatment workgroup, including a presentation of the final draft of a report on Quality Measures in Newborn Screening; and the Education and Training workgroup, including a presentation of the final draft of a