

that the new drug application (NDA) for LINZESS (NDA 202811) was submitted on August 9, 2011.

3. *The date the application was approved:* August 30, 2012. FDA has verified the applicant's claim that NDA 202811 was approved on August 30, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 945 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 July 22, 2014. 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 19, 2014. 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: May 15, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-11926 Filed 5-22-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-E-0034]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for INLYTA 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 Patents and Trademarks, 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, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6257, Silver Spring, MD 20993-0002, 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 Patents and Trademarks 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 INLYTA (axitinib). INLYTA is indicated for treatment of advanced renal cell carcinoma after failure of one prior systemic therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INLYTA (U.S. Patent No. 6,534,524) from Agouron Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of INLYTA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INLYTA is 3,699 days. Of this time, 3,410 days occurred during the testing phase of the regulatory review period, while 289 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:* December 13, 2001. The applicant claims December 14, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 13, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 14, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for INLYTA (NDA 202324) was submitted on April 14, 2011.

3. *The date the application was approved:* January 27, 2012. FDA has verified the applicant's claim that NDA 202324 was approved on January 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,763 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 July 22, 2014. 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 19, 2014. 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: May 15, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–11925 Filed 5–22–14; 8:45 am]

**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval: Public Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than June 23, 2014.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Delta States Rural Development Network Grant Program Performance Improvement Measurement System Measures OMB No. 0915-xxxx—New

*Abstract:* The Delta States Rural Development Network Grant Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular

disease, diabetes, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of programs are collaboration, adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.

*Need and Proposed Use of the Information:* For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Public Law 103–62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to the Office's progress toward meeting set goals. Summary of Prior Comments and Agency Response: A 60-day Federal Register Notice was published in the *Federal Register* on February 11, 2014 (79 FR 8196). There were no comments.

*Likely Respondents:* Delta States Rural Development Network Grant Program award recipients.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Delta States Rural Development Network Program Performance Measures .....	12	1	12	6	72
Total .....	12	1	12	6	72