

CDC is also requesting an adjustment to the burden associated with reports of communicable disease or death from domestic conveyances. CDC is reducing the burden from 15 minutes per report to 7 minutes. This is due to the facilitation of reporting using electronic means, *i.e.* Air Traffic Control and the Domestic Events Network for domestic flights, rather than the hard copy Master of Vessel or Conveyance Illness Report.

Finally, CDC is requesting the addition of the Passenger Locator Form to this information collection. CDC currently has approval to collect the Passenger Locator Form from travelers aboard international flights under OMB Control Number 0920-0134. CDC is requesting approval to collect passenger contact and locating information for travelers aboard domestic flights within the United States.

The resulting change in burden is a reduction of 3,611 hours.

*Estimated Annualized Burden Hours*

CDC anticipates this information collection will result in 90 total burden hours from 1,000 respondents. There is no burden to respondents other than the time required to complete and send the requested information to CDC. The estimated annualized burden is 90 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Master of a vessel or person in charge of a conveyance.	42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel.	200	1	7/60
Traveler .....	Passenger Locator Form .....	800	1	5/60

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2014-E-0308 and FDA-2014-E-0309]

**Determination of Regulatory Review Period for Purposes of Patent Extension; FULYZAQ**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for FULYZAQ 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 February 8, 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 June 7, 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 Nos. FDA-2014-E-0308 and FDA-2014-E-0309 for “Determination of Regulatory Review Period for Purposes of Patent Extension; FULYZAQ.” Received comments will be placed in the dockets 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 FULYZAQ (crofelemer). FULYZAQ is indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. Subsequent to this approval, the USPTO received a patent term restoration application for FULYZAQ (U.S. Patent No. 7,323,195) from Napo Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 23, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of FULYZAQ 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 FULYZAQ is 7,784 days. Of this time, 7,391 days occurred during the testing phase of the regulatory review period, while 393 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:* September 11, 1991. The applicant claims August 14, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 11, 1991, which was 30 days after FDA receipt of the first IND from the sponsor for this new drug.

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 5, 2011. The applicant claims December 16, 2011, as the date the new drug

application (NDA) for FULYZAQ (NDA 202292) was initially submitted. However, FDA records indicate that NDA 202292 was submitted on December 5, 2011.

3. *The date the application was approved:* December 31, 2012. FDA has verified the applicant's claim that NDA 202292 was approved on December 31, 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.

##### 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. 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: December 4, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-E-0265]

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

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

**ACTION:** Notice.