

Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-test	5	1	5	1.5	7.50
Interviews	135	1	135	1.5	202.50
Total					210

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-31100 Filed 12-9-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-E-1573]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VERAFLUX 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 U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that animal 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 No. FDA-2013-E-1573 for “Determination of Regulatory Review Period for Purposes of Patent Extension; VERAFLUX”. 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product VERAFLOR (pradofloxacin). VERAFLOR is indicated for treatment of skin infections in cats caused by susceptible strains of *Pasteurella multocida*, *Streptococcus canis*, *Staphylococcus aureus*, *Staphylococcus felis*, and *Staphylococcus pseudintermedius*. Subsequent to this approval, the USPTO received a patent term restoration application for VERAFLOR (U.S. Patent No. 6,323,213) from Bayer Animal Health GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for

patent term restoration. In a letter dated March 26, 2014, FDA advised the USPTO that this animal drug product had undergone a regulatory review period and that the approval of VERAFLOR 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 VERAFLOR is 3,285 days. Of this time, 3,235 days occurred during the testing phase of the regulatory review period, while 50 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 FD&C Act (21 U.S.C. 355(i)) became effective:* November 12, 2003. The applicant claims July 31, 2002, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the INAD effective date was November 12, 2003, which was the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug.
2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act (21 U.S.C. 360b):* September 19, 2012. FDA has verified the applicant's claim that the new animal drug Application (NADA) for VERAFLOR (NADA 141-344) was submitted on September 19, 2012.
3. *The date the application was approved:* November 7, 2012. FDA has verified the applicant's claim that NADA 141-344 was approved on November 7, 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. In its application for patent extension, this applicant seeks 1,901 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. 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

Viral Hepatitis Action Plan—Community Stakeholder Activities Request for Information

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is seeking public input from state and local governments, community based organizations, academic institutions, professional organizations, advocacy groups, private industry, and other non-federal stakeholders on activities undertaken in 2014-2015 in support of the goals of the national Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis.

DATES: All responses must be received at the address provided below, no later than 5:00 p.m. ET on February 8, 2016.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to Corinna.Dan@hhs.gov. Written responses should be addressed to: U.S. Department of Health and Human Services, 200 Independence Ave. SW., Room 443H, Washington, DC 20201. Attention: VHAP—2015RFI

FOR FURTHER INFORMATION CONTACT: Corinna Dan, RN, MPH, Office of HIV/AIDS and Infectious Disease Policy, (202) 401-9581.

SUPPLEMENTARY INFORMATION: The updated comprehensive national action plan, *Combating the Silent Epidemic of*