DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–1233]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZUPREVO 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 animal 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 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 ZUPREVO (tildipirosin). ZUPREVO is an animal drug product indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica, P. multocida,* and *H. somni*. Subsequent to this approval, USPTO received a patent term restoration application for ZUPREVO (U.S. Patent No. 6,514,946) from Koueki Zaidan Hojin Biseibutsu Kagaku Kenkyu Kai, and USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2013, FDA advised USPTO that this animal drug product had undergone a regulatory review period and that the approval of ZUPREVO represented the first permitted commercial marketing or use of the product. Thereafter, USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZUPREVO is 2,903 days. Of this time, 2,842 days occurred during the testing phase of the regulatory review period, while 61 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:* June 4, 2004. The applicant claims March 8, 2004, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the INAD effective date was June 4, 2004, which was the date a major health or environmental effects test is begun or the date on which the Agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier.

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):* March 15, 2012. The applicant claims March 14, 2012, as the date the new animal drug application (NADA) for ZUPREVO (NADA 141–334) was initially submitted. However, FDA records indicate that NADA 141–334 was submitted on March 15, 2012.

3. *The date the application was approved:* May 14, 2012. FDA has verified the applicant's claim that NADA 141–334 was approved on May 14, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,524 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 August 11, 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 December 9, 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: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13637 Filed 6–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; HIV Study in Blood Donors From Five Chinese Regions

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments And For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301–435–0065, or Email your request, including your address to: *glynnsa@nhlbi.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: HIV Study in Blood Donors from Five Chinese Regions, 0925–0596 reinstatement with change, National Heart, Lung and Blood Institute (NHLBI).

Need and Use of Information Collection: This Study is a reinstatement of OMB Number: 0925–0596 expiration date, January 31, 2012. To better understand the diversifying and changing Human Immunodeficiency Virus (HIV) epidemic, and contemporary HIV risk factors, especially those associated with recent HIV infections, this HIV risk factor study in China is proposed as part of the Recipient Epidemiology and Donor Evaluation Study-III (REDS–III). The major objectives of the study will be to evaluate the proportion of blood donors in China who test positive for HIV and have acquired their infection recently or more remotely; the risk of releasing a blood product that contains HIV (HIV residual risk); and the risk factors associated with HIV infection in China. The study will also assess the frequency of distinct HIV–1 viral lineages and drug resistant mutations among HIV-positive blood donors. In 2011, there were 780,000 people infected with HIV in China and it is estimated that over 300,000 HIV infected people in China are not aware of their infection status. The large migrating population and the complexity of HIV transmission routes in China make it difficult to implement a comprehensive and effective national HIV control strategy. Risk factors for infections can change over time; thus, identifying factors that contribute to the recent spread of HIV in a broad cross-section of an otherwise unselected general population, such as blood donors, is highly important for obtaining a complete picture of the epidemiology of HIV infection in China. Because the pace of globalization means infections can cross borders easily, the study objectives have direct relevance for HIV control in the U.S. and globally. Recent years have seen an increase in blood donations from repeat donors in most Chinese regions. This increase permits longer-term follow-up and testing of repeat donors which allow for calculation of new HIV infection rates and residual risks. The HIV data, for both recently and remotely acquired infections, from the proposed study will complement existing data on HIV risks obtained from general and high risk populations to provide comprehensive HIV surveillance data for China. This study will also monitor genetic characteristics of recently acquired infections through genotyping and drug resistance testing, thus serving a U.S. and global public health imperative to monitor the genotypes of HIV that have recently been transmitted. For HIV, the additional monitoring of drug resistance patterns in newly acquired infection is critical to determine if currently available antiretroviral medicines are capable of combating infection. Genotyping and host response information are scientifically important not only to China, but to the U.S. and other nations since they provide a broader global understanding of how to most effectively manage and potentially prevent HIV, for example through vaccine development. Efforts to develop vaccines funded by the National Institutes of Health and other U.S.-based organizations may directly benefit from the findings of this study.

Blood donors are tested for transfusion-transmissible infections including HIV when they present to donate, and test result information as well as demographic data will be routinely collected in a database at the five blood centers participating in REDS–III studies (located in the cities of Chongqing, Liuzhou, Luoyang, Mianyang, and Urumqi). These data will allow for calculation of HIV incidence, prevalence, and residual risk. Additionally, a case-control study will be conducted over a 2 and 1/2 year period to evaluate the risk factors associated with HIV infection among blood donors. Cases will be defined as potential donors who deny risks on the donor screening questionnaire but are found to be positive on HIV testing (their donation is discarded). HIV-positive donors who gave blood at one of the five blood centers as stated above (primary sites) or at blood centers located in the Guangxi Autonomous Region (peripheral sites, recruited through the Guangxi CDC for this study only but not other REDS–III studies) will be eligible to participate and complete a Risk Factor Questionnaire that will assess general demographic and risk factor information pertinent to HIV infection. Controls will be negative for HIV on confirmatory testing. Assuming 50% response rate, it is anticipated that 390 HIV-positive donors and 960 controls will participate in the case control study. The results of this study will contribute to global HIV surveillance and prevention, provide a broader global understanding of HIV epidemiology, and support public health efforts to most effectively manage and potentially prevent HIV transmission both worldwide and in the U.S.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total