

under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of feed facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed.

The FDA Food Safety Modernization Act passed on January 4, 2011, calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of food and feed safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal Agencies to ensure credibility of food and feed programs within the IFSS.

II. Significance of Feed Program Standards

The AFRPS provide a uniform and consistent approach to feed regulation in the United States. Implementation of the draft feed program standards is voluntary. States implementing the

standards will identify and maintain program improvements that will strengthen the safety and integrity of the U.S. animal feed supply.

The feed standards are the framework that each State should use to design, manage, and improve its feed program. The standards include the following: (1) Regulatory foundation; (2) training; (3) inspection program; (4) auditing; (5) feed-related illness or death and emergency response; (6) enforcement program; (7) outreach activities; (8) budget and planning; (9) assessment and improvement; (10) laboratory services; and (11) sampling program.

Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a State program voluntarily agrees to implement the feed standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard.

The feed standards package includes forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates provided with the feed standards. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the feed standards must be maintained in good order by the State

program and must be available to verify the implementation of each standard. The feed standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

In the first year of implementation, the State program uses the self-assessment worksheets to determine if the requirements for each standard are fully met, partially met, or not met. The self-assessments are used to develop an improvement plan for fully implementing the requirements of the 11 standards. Second and third-year assessments will provide progress evaluation.

Although FDA plans to provide financial support to State programs that implement the feed standards, funding opportunities are contingent upon the availability of funds. Funding opportunities may be only available to State feed regulatory programs that currently have an FDA feed inspection contract. State programs receiving financial support to implement the feed standards will be audited by FDA.

III. Electronic Access

Persons with access to the Internet may submit requests for a single copy of the current feed standards from ORAHQOPIO@fda.hhs.gov. Please note that due to editorial revisions and public comments, the final standards may differ from the copy you receive.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Employee	40	1	40	3,000	120,000

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

The burden has been calculated to 3,000 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 11 standards contained in AFRPS. FDA recognizes that full use and implementation of the feed standards by State feed programs will occur over many years and the number of years to fully implement the feed standards will vary among States.

Dated: April 6, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-08331 Filed 4-11-16; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos.: FDA-2014-E-2355; FDA-2014-E-2356; and FDA-2014-E-2357]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for

GAZYVA 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 biological 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 June 13, 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 October 11, 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-2355; FDA-2014-E-2356; and FDA-2014-E-2357 for "Determination of Regulatory Review Period for Purposes of Patent Extension; GAZYVA."

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 and 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product GAZYVA (obinutuzumab). GAZYVA is indicated, in addition with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia. Subsequent to this approval, the U.S. Patent and Trademark Office (USPTO) received patent term restoration applications for GAZYVA (U.S. Patent Nos. 6,602,684; 7,517,670; and 8,021,856) from Genentech, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human biological product had undergone a

regulatory review period and that the approval of GAZYVA 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 GAZYVA is 1,698 days. Of this time, 1,504 days occurred during the testing phase of the regulatory review period, while 194 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 (21 U.S.C. 355(i)) became effective:* March 11, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 11, 2009.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* April 22, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for GAZYVA (BLA 125486) was initially submitted on April 22, 2013.

3. *The date the application was approved:* November 1, 2013. FDA has verified the applicant's claim that BLA 125486 was approved on November 1, 2013.

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 929, 946, or 484 days, respectively, 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.

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08338 Filed 4–11–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Stakeholder Listening Session in Preparation for the 69th World Health Assembly

Time and date: May 6th, 2016, 10:30 a.m.–12:00 Noon EST.

Place: Hubert H. Humphrey Building, Room 505A, 200 Independence Ave. SW., Washington, District of Columbia 20201.

Status: Open, but requiring RSVP to OGA.RSVP@hhs.gov.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 69th World Health Assembly—will hold an informal Stakeholder Listening Session on *Friday, May 6, 10:30 a.m.–12:00 noon*, in Conference Room 505A of the Hubert H. Humphrey Building, 200 Independence Ave. S.W., Washington, DC 20201.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation for the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 69th World Health Assembly. Your input will contribute to U.S. positions as we negotiate with our international colleagues at the World Health Assembly these important health topics.

The listening session will be organized by agenda item, and participation is welcome from all individuals, particularly members of stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 69th World Health Assembly can be found at this Web site: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_1-en.pdf.

RSVP: Due to security restrictions for entry into the HHS Hubert H. Humphrey

Building, we will need to receive RSVPs for this event. Please send your full name and organization to OGA.RSVP@hhs.gov. If you are *not* a U.S. citizen, please note this in the subject line of your RSVP, and our office will contact you to gain additional biographical information for your clearance. Please RSVP no later than Wednesday, April 27, 2016.

Written comments are welcome and encouraged, even if you are planning on attending in person. Please send these to the email address: OGA.RSVP@hhs.gov.

We look forward to hearing your comments relative to the 69th World Health Assembly agenda items.

Dated: March 14, 2016.

Jimmy Kolker,

Assistant Secretary for Global Affairs.

[FR Doc. 2016–08287 Filed 4–11–16; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Establishment of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 and Solicitation of Nominations for Membership; Correction

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Health and Human Services published a notice in the **Federal Register**, dated March 17, 2016, to announce the establishment of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee) and invites nominations for membership. This notice contained incorrect information.

FOR FURTHER INFORMATION CONTACT: Emmeline Ochiai, email address: HP2030@hhs.gov.

Correction

In the **Federal Register**, dated March 17, 2016, on page 14455, correct the Title to read:

Announcement of Intent to Establish the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 and Solicitation of Nominations for Membership and correct the **SUMMARY** to read:

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces its intent