

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]

**BILLING CODE 4164–01–P**

## 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](mailto: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](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](mailto: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](mailto: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](mailto: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