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 VIZAMYL (flumetamol F18 injection). VIZAMYL is a radioactive diagnostic agent indicated for Positron Emission Tomography imaging of the brain to estimate β amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease or other causes of cognitive decline. Subsequent to this approval, the USPTO received a patent term restoration application for VIZAMYL (U.S. Patent No. 7,270,800) from GE Healthcare Limited, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 27, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VIZAMYL 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 VIZAMYL is 1,541 days. Of this time, 1,176 days occurred during the testing phase of the regulatory review period, while 365 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:* August 8, 2009. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on August 8, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 26, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for VIZAMYL (NDA 203137) was initially submitted on October 26, 2012.

3. *The date the application was approved:* October 25, 2013. FDA has verified the applicant's claim that NDA 203137 was approved on October 25, 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 application for patent extension, this applicant seeks 951 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 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31401 Filed 12–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4462]

Point of Care Prothrombin Time/International Normalized Ratio Devices for Monitoring Warfarin Therapy; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled

''Point of Care Prothrombin Time/International Normalized Ratio Devices for Monitoring Warfarin Therapy.'' The purpose of this workshop is to discuss and receive input from stakeholders regarding approaches to the analytical and clinical validation of point of care (POC) Prothrombin Time/International Normalized Ratio (PT/INR) in vitro diagnostic devices for improved clinical management of warfarin therapy in addition to describing the FDA's process for facilitating the development of safe and effective POC and patient self-testing PT/INR devices. The goal of the workshop is to seek and identify potential solutions to address the scientific and regulatory challenges associated with POC PT/INR devices to ensure safety and effectiveness.

DATES: The public workshop will be held on January 25, 2016, from 8 a.m. to 5 p.m. Submit either electronic or written comments on the public workshop by February 25, 2016.

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–2015–N–4462 for ''Point of Care Prothrombin Time/International Normalized Ratio Devices for Monitoring Warfarin Therapy.'' 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.

The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Rachel Goehe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5533, Silver Spring, MD 20993, 240–402–6565, email: *Rachel.Goehe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Warfarin, an oral vitamin K antagonist, is a commonly prescribed anticoagulant drug used to reduce the risk of thromboembolic events. Warfarin inhibits the synthesis of clotting factors II, VII, IX, and X, in addition to the naturally occurring endogenous anticoagulant proteins C and S. The response of individual patients to warfarin is highly variable because of factors such as diet, age, and interaction with other drugs. As a consequence, it is important that warfarin dosage be tailored individually to maintain clinical benefit. The PT test is used to determine a patient's clotting time, which the Clinical and Laboratory Standards Institute defines as the time in seconds required for a fibrin clot to form in a plasma sample after tissue thromboplastin and an optimal amount of calcium chloride have been added to the sample. It is well-recognized that a PT result obtained with one test system cannot be compared to a PT result obtained with another test system because of the variety of thromboplastins used in different test systems. Therefore, PT test results are converted into a standardized unit known as the INR, which was adopted by the World Health Organization with the intent to reduce intersystem variation in test results. The INR result is used to monitor patients' response to warfarin.

POC PT/INR devices offer an alternative to laboratory-based testing and venipuncture, enabling a rapid INR determination from a finger stick sample of whole blood. POC devices can be

used in a variety of settings including, but not limited to, physician's office laboratory, anti-coagulation clinic, patient bedside, hospital emergency department, and prescription home use. The purpose of POC PT/INR testing is to monitor warfarin and to provide immediate information to physicians about the patient's anticoagulation status so that this information can be integrated into appropriate treatment decisions that can improve patient outcomes. POC PT/INR testing is increasingly being viewed as a testing modality with performance expectations similar to that of traditional laboratory testing. From a regulatory standpoint, POC PT/INR devices have been reviewed and cleared for prescription use under appropriate professional supervision or prescription home use (patient self-testing), depending on the claimed intended use. For this workshop, both settings will be open for discussion.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of presentations covering the topics listed in this document. Following the presentations, there will be a moderated panel discussion where participants will be asked to provide their perspectives. The workshop panel discussion will focus on identifying potential solutions to address the scientific and regulatory challenges associated with POC PT/INR devices. In advance of the meeting, FDA plans to post a discussion paper outlining FDA's current thinking on the various topics mentioned in the following list, and invite comment on this from the community.

Topics to be discussed at the public workshop include, but are not limited to, the following:

- Current regulatory process involved with the clearance of POC PT/INR devices.
- Current benefit/risk balance of POC PT/INR devices.
- Technological differences amongst marketed POC PT/INR devices, advantages and limitations of each technology, and comparability of test results obtained using different technologies.
- Challenges associated with correlating results from whole blood POC PT/INR devices to conventional plasma-based laboratory tests.
- Appropriate study design for validation and usability studies from the perspectives of the Agency, manufacturers and end users to help improve our understanding of the accuracy, reliability and safety of POC PT/INR devices.
- Types of quality control and the test system elements assessed by the controls.
- Challenges associated with different sample matrices (venous, fingerstick, arterial).

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., January 15, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, 301–796–5661, email: *Susan.Monahan@fda.hhs.gov* no later than January 11, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan (contact for special accommodations) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the workshop Web page after January 18, 2016. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: December 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31404 Filed 12–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–1575]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RAXIBACUMAB 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 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 February 16, 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 13, 2016. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.