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Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 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 RAPIVAB (peramivir). RAPIVAB is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. Subsequent to this approval, the USPTO received patent term restoration applications for RAPIVAB (U.S. Patent Nos. 6,503,745 and 6,562,861) from BioCryst Pharmaceuticals, Inc., and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated April 29, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RAPIVAB 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 RAPIVAB is 3,287 days. Of this time, 2,925 days occurred during the testing phase of the regulatory review period, while 362 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:*

December 21, 2005. FDA has verified the BioCryst Pharmaceuticals, Inc. claims that December 21, 2005, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 23, 2013. FDA has verified the applicant’s claims that the new drug application (NDA) for RAPIVAB (NDA 206426) was initially submitted on December 23, 2013.

3. *The date the application was approved:* December 19, 2014. FDA has verified the applicant’s claim that NDA

206426 was approved on December 19, 2014.

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 1,824 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, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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 <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-25676 Filed 11-27-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

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

“Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology.” The purpose of the public workshop is to engage stakeholders and solicit input from experts in oncology precision medicine on how to best weigh and evaluate evidence for classification and interpretation of sequencing results for precision oncology.

DATES: The public workshop will be held on January 29, 2018, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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

FOR FURTHER INFORMATION CONTACT: Hisani Madison, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5547, Silver Spring, MD 20993, 240–402–6581, hisani.madison@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The goal of precision oncology is to use a cancer patient’s genetic data to help determine which therapeutic(s) might be most effective in treating their disease. Next generation sequencing is increasingly employed in oncology because the technology can be used to screen a large number of mutations simultaneously to optimize and personalize patient care. The increasing number of reported mutations may lead to uncertainty for clinicians in the interpretation and prioritization of the variants with respect to the clinical significance and optimal course of action, respectively.

In January 2017, the Association for Molecular Pathology, the American Society of Clinical Oncology, and the College of American Pathologists published a joint consensus recommendation for standards and guidelines for the interpretation and reporting of sequence variants in cancer. However, the implementation of these recommendations is not consistently applied across all stakeholders. FDA is holding this public workshop to engage stakeholders and solicit input from

internal and external experts in precision oncology to discuss how genetic sequencing data is best implemented in patient management so that innovative regulatory strategies can be advanced to support the development of safe and effective precision-based drugs and devices for marketing.

II. Topics for Discussion

Topics for discussion at the public workshop include:

- An overview of the state of the science for sequence variant classification in oncology and its practical use in treating patients;
- The level of evidence required for reporting variants and/or guiding patient treatment;
- Best practices for the use of public/private databases for variant classification and interpretation in oncology; and
- Future directions for data sharing, standardization, and establishing consistency in precision oncology.

The workshop will include a series of brief presentations to provide information to frame the main topics and interactive discussions via several panel sessions. Following the presentations, there will be a moderated discussion where speakers and additional panelists may be asked to provide their individual perspectives.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <https://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.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 19, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Peggy Roney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5671, email: Peggy.Roney@fda.hhs.gov no later than January 10, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration Web page after January 10, 2018.

Organizations are requested to view using one connection per location.

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 https://www.adobe.com/go/connectpro_overview. FDA has verified the Web site addresses in this document, 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 of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

Dated: November 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25584 Filed 11–27–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–2374]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for YONDELIS and is publishing this notice of that determination as required