''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]

BILLING CODE 4164–01–P

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

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 drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. 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 May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2016–E–2374 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; YONDELIS.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

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 YONDELIS (trabectedin). YONDELIS is indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen. Subsequent to this approval, the USPTO

received a patent term restoration application for YONDELIS (U.S. Patent No. 7,420,051) from Pharma Mar, S.A., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 25, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of YONDELIS 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 YONDELIS is 7,107 days. Of this time, 6,773 days occurred during the testing phase of the regulatory review period, while 334 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:* May 10, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 10, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 24, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for YONDELIS (NDA 207953) was initially submitted on November 24, 2014.

3. *The date the application was approved:* October 23, 2015. FDA has verified the applicant's claim that NDA 207953 was approved on October 23, 2015.

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 1,471 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. 2017–25683 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0384]

Pediatric Information for X-Ray Imaging Device Premarket Notifications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' This guidance document outlines FDA's current thinking on information that should be provided in premarket notification submissions for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. FDA intends for this guidance to minimize uncertainty during the premarket review process of premarket notification submissions for x-ray imaging devices for pediatric use to encourage the inclusion of pediatric indications for use for x-ray imaging device premarket notification submissions and to provide recommendations on information to support such indications. Both new devices and modifications of existing x-ray imaging devices that require submission of a new premarket notification are included within the scope of this guidance document, regardless of whether the device is a complete x-ray imaging system, a component part of an x-ray imaging device, or an accessory (*e.g.,* detectors and software).

DATES: The announcement of the guidance is published in the **Federal Register** on November 28, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–