

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 product 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 KOVALTRY (antihemophilic factor (recombinant)). KOVALTRY is indicated for use in adults and children with hemophilia A for: (1) On-demand treatment and control of bleeding episodes; (2) perioperative management of bleeding; and (3) routine prophylaxis to reduce the frequency of bleeding episodes. Subsequent to this approval, the USPTO received a patent term restoration application for KOVALTRY (U.S. Patent No. 5,804,420) from Bayer HealthCare LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 14, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of KOVALTRY 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 KOVALTRY is 2,478 days. Of this time, 2,021 days occurred during the testing

phase of the regulatory review period, while 457 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:* June 5, 2009. FDA has verified the Bayer HealthCare LLC's claim that the date the investigational new drug application became effective was on June 5, 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):* December 16, 2014. FDA has verified the applicant's claim that the biologics license application (BLA) for KOVALTRY (BLA 125574/0) was initially submitted on December 16, 2014.

3. *The date the application was approved:* March 16, 2016. FDA has verified the applicant's claim that BLA 125574/0 was approved on March 16, 2016.

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 1,466 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: September 29, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

### Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

**DATES:** The meeting will be held on November 6, 2017, from 8 a.m. to 5 p.m., and on November 7, 2017, from 8 a.m. to 11:20 a.m.

**ADDRESSES:** Heifer Village, One World Avenue, Little Rock, AR 72202. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm> and <https://www.heifer.org/what-you-can-do/experience-heifer/heifer-village/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993-0002, 301-796-8892, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <https://>

[www.fda.gov/AdvisoryCommittees/default.htm](http://www.fda.gov/AdvisoryCommittees/default.htm) and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On November 6, 2017, the SAB Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the Division of Systems Biology Subcommittee and the Subcommittee Site Visit Report and a response to this review. There will be updates from the NCTR Research Divisions and a public comment session.

On November 7, 2017, the Center for Biologics and Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Tobacco Products, Center for Veterinary Medicine, and the Office of Regulatory Affairs will each briefly discuss their center-specific research strategic needs and potential areas of collaboration.

Following an open discussion of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at NCTR at the end of each day.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* On November 6, 2017, from 8 a.m. to 5 p.m., and November 7, 2017, from 8 a.m. to 11:20 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 30, 2017. Oral presentations from the public will be scheduled on November 6, 2017, between approximately 1:15 p.m. to 2:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and

submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 23, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 30, 2017.

*Closed Committee Deliberations:* On November 6, 2017, from 5 p.m. to 5:30 p.m., and November 7, 2017, from 11:20 a.m. to 12 noon, the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Donna Mendrick at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 29, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-E-1298]

**Determination of Regulatory Review Period for Purposes of Patent Extension; IMPELLA 2.5 SYSTEM**

**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 IMPELLA 2.5 SYSTEM 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 medical device.

**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 December 4, 2017. 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 April 3, 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 December 4, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 4, 2017. 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