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 will be 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 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).


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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 re-determination 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
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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has determined for the medical device IMPELLA 2.5 SYSTEM that this medical device had undergone a regulatory review period and that the approval of IMPELLA 2.5 SYSTEM represented the first permitted commercial marketing or use of the product. Therefore, 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 IMPELLA 2.5 SYSTEM is 3,227 days. Of this time, 2,858 days occurred during the testing phase of the regulatory review period, while 369 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(j)) involving this device became effective: May 24, 2006. FDA has verified the applicant’s claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective was May 24, 2006.

2. The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e): March 20, 2014. FDA has verified the applicant’s claim that the premarket approval application (PMA) for IMPELLA 2.5 SYSTEM (PMA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET No. FDA–2016–D–4482]

Clarification of the Food and Drug Administration and Environmental Protection Agency Jurisdiction Over Mosquito-Related Products; Guidance for Industry; 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 a guidance for industry #236 entitled “Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products.” This guidance provides information regarding regulatory oversight of mosquito-related products, defined as those articles for use in or on mosquitoes. We are clarifying circumstances under which such products are regulated by the Food and Drug Administration (FDA) as new animal drugs under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and other circumstances under which such products are regulated by the Environmental Protection Agency (EPA) as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

DATES: The announcement of the guidance is published in the Federal Register on October 5, 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–2016–D–4482 for “Regulation of Mosquito-Related Products.” Received comments 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 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