information to an incomplete FCN submission, an amendment to a pre-notification consultation, or an amendment to a master file in support of an FCN. We calculate a reporting burden of 0.5 hours per response, for a total burden of 50 hours.

In row 8, we estimate one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. We calculate a reporting burden of 10,995 hours per response, for a total burden of 10,995 hours.

In row 9, we estimate 10 respondents will utilize the recommendations in the guidance document entitled, “Use of Recycled Plastics in Food Packaging; Chemistry Considerations,” to develop the additional information for one such submission annually, for a total of 10 responses. We calculate a reporting burden of 25 hours per response, for a total burden of 250 hours.

Finally, in row 10, we estimate 2 respondents will utilize the recommendations in the draft guidance, once finalized, entitled, “Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk,” to develop the additional information for one such submission annually, for a total of 2 responses. We calculate a reporting burden of 5 hours per response, for a total burden of 10 hours.

Dated: February 6, 2019.
Lowell J. Schiller,
Acting Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2017–E–6739]

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

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 ZEJULA 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 (see the SUPPLEMENTARY INFORMATION section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 15, 2019. 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 August 12, 2019. 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 April 15, 2019. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2019. 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–2017–E–6739 for “Determination of Regulatory Review Period for Purposes of Patent Extension; ZEJULA.” 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 docket, 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 notice, into the “Search” box and follow the prompts and/or go to the Dockets Management
had undergone a regulatory review period and that the approval of ZEJULA 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 ZEJULA is 3,234 days. Of this time, 3,086 days occurred during the testing phase of the regulatory review period, while 148 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 (FD&C Act) (21 U.S.C. 355(i)) became effective: May 21, 2008. The applicant claims May 22, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 21, 2008, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

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 31, 2016. FDA has verified the applicant’s claim that NDA 208447 was approved on March 27, 2017. FDA has determined that the application was initially submitted on March 27, 2017 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, Rockville, MD 20852.


Lowell J. Schiller, Acting Associate Commissioner for Policy.

[FR Doc. 2019–02036 Filed 2–11–19; 8:45 am]

BILING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Application Review (2019/05).

Date: March 5–7, 2019.

Time: 6:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton Memphis East, 5069 Sanderlin Avenue, Memphis, TN 38117.

Contact Person: John P. Holden, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, (301) 496–8775 john.holden@nih.gov.