



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-E-2529]

Determination of Regulatory Review Period for Purposes of Patent Extension; BRIVIACT ORAL SOLUTION, New Drug Application 205838

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 BRIVIACT ORAL SOLUTION 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2529 for "Determination of Regulatory Review Period for Purposes of Patent Extension; BRIVIACT ORAL SOLUTION." 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 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, if a patent is eligible for extension under these acts, the 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 the drug product "was approved" within the meaning of 35 U.S.C. 156. In the case of a drug recommended for controls under the Controlled Substances Act (CSA), for purposes of patent term extension, a drug is considered to have been approved on the later of the date the application to market the drug is approved or the date of issuance of the interim final rule controlling the drug. (See 35 U.S.C. 156(i)). 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 BRIVIACT ORAL SOLUTION (brivaracetam) under new drug application (NDA) 205838. BRIVIACT ORAL SOLUTION is indicated for adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. Subsequent to this approval, the USPTO received a patent term restoration application for BRIVIACT ORAL SOLUTION (U.S. Patent No. 8,492,416) from UCB Biopharma SPRL and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 18, 2017, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BRIVIACT ORAL SOLUTION 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 BRIVIACT ORAL SOLUTION is 4,293 days. Of this time, 3,753 days occurred during the testing phase of the regulatory review period, while 540 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:* August 12, 2004. The applicant claims December 22, 2010, as the date the investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND submitted for investigation of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for brivaracetam was August 12, 2004, which was 30 days after FDA receipt of this first IND. This is the same IND and the same date FDA determined was the beginning of the regulatory review period for BRIVIACT ORAL TABLETS approved under NDA 205836 and for BRIVIACT INJECTION approved under NDA 205837. The regulatory review period determinations for BRIVIACT ORAL TABLETS and BRIVIACT INJECTION are published in this issue of the *Federal Register*.
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 20, 2014. FDA has verified the

applicant's claim that the NDA for BRIVIACT ORAL SOLUTION (NDA 205838) was initially submitted on November 20, 2014.

3. *For a drug recommended for controls under the CSA, the later of the date the NDA was approved under section 505 of the FD&C Act or the date of issuance of the interim final rule controlling the drug:* May 12, 2016. FDA has verified the applicant's claim that NDA 205838 was approved on February 18, 2016. FDA has also verified that the date of issuance of the interim final rule controlling the drug, placing BRIVIACT ORAL SOLUTION (brivaracetam) in schedule V of the CSA as revised by the Improving Regulatory Transparency for New Medical Therapies Act, was May 12, 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 698 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: December 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-26814 Filed: 12/11/2019 8:45 am; Publication Date: 12/12/2019]