DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the West Valley Demonstration Project in West Valley, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Grady Calhoun, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 513–533–6800. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION: On October 25, 2019, as provided for under 42 U.S.C. 7384*l*(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at the West Valley Demonstration Project in West Valley, New York, during the period from January 1, 1969, through December 31, 1973, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on November 24, 2019. Therefore, beginning on November 24, 2019, members of this class of employees, defined as reported in this notice, became members of the SEC.

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

John J. Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2019–26747 Filed 12–11–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–0020; Docket No. CDC–2019–0109]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period; Withdrawal.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the withdrawal of the notice published under the same title on December 6, 2019 for public comment.

DATES: December 12, 2019.

FOR FURTHER INFORMATION CONTACT: Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: On December 6, 2019 CDC published a notice in the **Federal Register** titled ''Proposed Data Collection Submitted for Public Comment and Recommendations'' (84 FR 66902). This notice with **Federal Register** Document 2019–26370 and Docket number CDC–2019–0109, was published prematurely and inadvertently. The notice is being withdrawn immediately for public comment. A new notice will be published at a later date for public comment.

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–26692 Filed 12–11–19; 8:45 am]

BILLING CODE 4163–18–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 February 10, 2020. 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 June 9, 2020. 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 February 10, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 10, 2020. 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 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, 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 12–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0417]

Request for Nominations on the National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve on the National Mammography Quality Assurance Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by January 13, 2020 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by January 13, 2020.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for a nonvoting industry representative should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Division of Management Services, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993, 301–796–5960, Fax: 301–847–8505, email: *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for a nonvoting industry representative on the National Mammography Quality Assurance Advisory Committee:

I. General Description of the Committee Duties

The Committee shall advise FDA on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in these areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication