

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Administration on Disabilities, President's Committee for People With Intellectual Disabilities

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The President's Committee for People with Intellectual Disabilities (PCPID) will host a webinar/conference call for its members to discuss the Committee's 2016 Report to the President (RTP). All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a discussion format.

**DATES:** Webinar: Monday, May 2, 2016 from 3:00 p.m. to 4:30 p.m. (EST).

**ADDRESSES:** Webinar Web page: [https://meetingserver.hhs.gov/orion/joinmeeting.do?ED=PkeE\\_dUKbJrkcq5Y9wSWvA==](https://meetingserver.hhs.gov/orion/joinmeeting.do?ED=PkeE_dUKbJrkcq5Y9wSWvA==).

#### FOR FURTHER INFORMATION AND

#### REASONABLE ACCOMMODATIONS NEEDS

**CONTACT:** Dr. MJ Karimi, PCPID Team Lead, 330 C Street SW., 1108A, Washington, DC 20201. Email: [MJ.Karimi@acl.hhs.gov](mailto:MJ.Karimi@acl.hhs.gov); telephone: 202-79-7374; fax: 202-205-0402.

#### SUPPLEMENTARY INFORMATION:

*Background:* The PCPID Committee Members met, on February 22-23, 2016, and discussed the following four focus areas that will be included on the 2016 RTP:

Family engagement early on in the process to support high expectations for students with disabilities  
Federal education policies and enforcement strategies to end segregation in schools  
Transition as a critical area for pathways to higher education and career development  
Self-determination/Supported decision-making from early childhood throughout the individual's lifespan  
The general purpose of this meeting is to provide the members with an opportunity to further discuss the recommendation sections of the 2016 RTP.

*Webinar/Conference Call:* The webinar is scheduled for May 2, 2016, 3:00 p.m. to 4:30 p.m. (EST) and may end early if discussions are finished.

*Instructions to Participate in the Webinar/Conference Call on Monday, May 2, 2016:*

1. Enter the following WebEx Link: [https://meetingserver.hhs.gov/orion/joinmeeting.do?ED=PkeE\\_dUKbJrkcq5Y9wSWvA==](https://meetingserver.hhs.gov/orion/joinmeeting.do?ED=PkeE_dUKbJrkcq5Y9wSWvA==)

2. Click on the "join" button on the page
3. Enter your name and email address
4. Follow additional instructions as provided by WebEx. This WebEx does not require a password.
5. Please dial: (888) 469-0940; Pass Code: 5315454 (you should put your phone on mute during the meeting)

*Background Information on the Committee:* The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: March 29, 2016.

**Aaron Bishop,**

*Commissioner, Administration on Disabilities.*

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**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-E-2325]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; BRINTELLIX

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for BRINTELLIX 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 (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by June 3, 2016. 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 October 3, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2014-E-2325 for "Determination of Regulatory Review Period for Purposes

of Patent Extension; BRINTELLIX". Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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 the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 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 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 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 FDA grants permission to market the drug 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 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 BRINTELLIX (vortioxetine hydrobromide). BRINTELLIX is indicated for treatment of major depressive disorder. Subsequent to this approval, the USPTO received a patent term restoration application for BRINTELLIX (U.S. Patent No. 7,144,884) from H. Lundbeck A/S, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BRINTELLIX 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 BRINTELLIX is 2,343 days. Of this time, 1,979 days occurred during the testing phase of the regulatory review period, while 364 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* May 4, 2007. FDA has verified the H. Lundbeck A/S claim that May 4, 2007, is the date the investigational new drug application) became effective.

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 2, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for BRINTELLIX (NDA 204447) was initially submitted on October 2, 2012.

3. *The date the application was approved:* September 30, 2013. FDA has verified the applicant's claim that NDA 204447 was approved on September 30, 2013.

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 1,353 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 ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (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 <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 29, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-07477 Filed 4-1-16; 8:45 am]

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