

## 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