

Amendment of the Constitution of the United States providing for women's suffrage."

The duties of the Commission, as written in the law, include: (1) To encourage, plan, develop, and execute programs, projects, and activities to commemorate the centennial of the passage and ratification of the 19th Amendment; (2) To encourage private organizations and State and local Governments to organize and participate in activities commemorating the centennial of the passage and ratification of the 19th Amendment; (3) To facilitate and coordinate activities throughout the United States relating to the centennial of the passage and ratification of the 19th Amendment; (4) To serve as a clearinghouse for the collection and dissemination of information about events and plans for the centennial of the passage and ratification of the 19th Amendment; and (5) To develop recommendations for Congress and the President for commemorating the centennial of the passage and ratification of the 19th Amendment.

#### Meeting Agenda for March 27, 2019

- Welcome and Introductions
- Executive Director update
- Subcommittee updates
- Public Comment Period
- Adjourn

#### Meeting Agenda for June 3, 2019

- Welcome and Introductions
- Commission business and administrative items
- Executive Director update
- Presentations from informative speakers
- Subcommittee updates
- Public Comment Period
- 2019 Meeting Schedule
- Adjourn

The meetings are open to the public, but preregistration is required. Any individual who wishes to attend the meeting should register via email at [kmoliver@blm.gov](mailto:kmoliver@blm.gov) or telephone 202-912-7510. Space is limited and requests to attend will be accommodated in the order they are received.

Interested persons may choose to make a public comment at the meeting during the designated time for this purpose. Public comments shall be limited by minutes based on the number of participants signed up to comment for the allotted time, and subject to agenda time changes based on the speed of the commission's work through the agenda. Speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may

submit written statements up to 30 days after the meeting.

Members of the public may also choose to submit written comments by mailing them to Kim Oliver, Designated Federal Officer, 1849 C Street NW, Room 7313, Washington, DC 20240, or via email at [kmoliver@blm.gov](mailto:kmoliver@blm.gov). Please contact Ms. Oliver at the email address above to obtain meeting materials. All written comments received will be provided to the Commission. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Individuals requiring special accommodations to access the public meeting should contact Ms. Oliver at least five business days prior to each meeting, so that appropriate arrangements can be made.

#### Public Disclosure of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Governmentwide Policy, General Services Administration.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2017-M-6870, FDA-2018-M-3584, and FDA-2018-M-3870]

### Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and

effectiveness summaries of approved PMAs through the internet and FDA's Dockets Management Staff.

**ADDRESSES:** You may submit either electronic or written comments at any time as follows:

#### 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. Since 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 Nos. FDA-2017-M-6870, FDA-2018-M-3584, and FDA-2018-M-3870 for "Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications." Received comments 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 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:**

Gretchen Oppen, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will

continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations (21 CFR 814.44(d) and 814.45(d)) provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of PMAs approved by CBER for which safety and effectiveness summaries were placed on the internet from October 1, 2017, through December 31, 2018. There were no denial actions during this period. The list provides the manufacturer’s name, the product’s generic name or the trade name, and the approval date.

**TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2017, THROUGH DECEMBER 31, 2018**

PMA No./Docket No.	Applicant	Trade name	Approval date
BP160122, FDA–2017–M–6870.	Ortho-Clinical Diagnostics, Inc .....	VITROS Immunodiagnostic Products HIV Combo Reagent Pack & VITROS Immunodiagnostic Products HIV Combo Calibrator.	December 13, 2017.
BP170122, FDA–2018–M–3584.	Avita Medical Americas, LLC .....	RECELL Autologous Cell Harvesting Device.	September 20, 2018.
BP170154, FDA–2018–M–3870.	Progenika Biopharma, S.A .....	ID CORE XT (Reagents and Analysis Software).	October 11, 2018.

**II. Electronic Access**

Persons with access to the internet may obtain the documents at <https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/default.htm>.

Dated: March 4, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for an opportunity for public comment on proposed data collection projects of the Paperwork

Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Before submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than May 6, 2019.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft