

revised reporting thresholds for certain data items. The Board also proposes to make changes to the reporting forms and instructions for the FR Y-9C, FR Y-9LP, and FR Y-9SP to implement accounting changes pertaining to equity securities under Accounting Standards update (ASU No. 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities."). The accounting changes pertaining to equity securities would be effective beginning with the reports reflecting the March 31, 2018, report date and June 30, 2018 for all other changes. The proposed changes include:

- Deleting and combining of certain data items pertaining to (1) Goodwill and Other intangible assets from Schedule HC, Balance Sheet; (2) U.S. Government agency obligations and structured financial products from Schedule HC-B, Securities; (3) Structured financial products and certain loans and the unpaid principal balance of such loans on Schedule HC-D, Trading Assets; (4) Certain over-the-counter derivatives on Schedule HC-L, Derivatives and Off-Balance sheet items, and (5) Purchased credit card relationships and nonmortgage servicing assets from Schedule HC-M, Memoranda;

- Deleting two preprinted captions for other noninterest income on Schedule HI, Income Statement and certain data items on Schedule HC-D, Trading Assets and Liabilities;

- Deleting Column B (Domestic Office) from Schedule HC-D, Trading Assets and Liabilities

- Reducing the reporting frequency from quarterly to semiannual and from quarterly to annual for certain data items on the FR Y-9C report

- Increasing and adding reporting thresholds for certain data items in four FR Y-9C schedules

- Revising the reporting forms and instructions to implement the reporting of equity securities under ASU-2016-01 and

- Moving "Goodwill" from Schedule HC to Schedule HC-M, Memoranda.

*Legal authorization and confidentiality:* The Board's Legal Division has determined that the FR Y-9 family of reports is authorized by section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)), section 10 of Home Owners' Loan Act (12 U.S.C. 1467a(b) and 1850a(c)(1)), section 165 of the Dodd-Frank Act (12 U.S.C. 5365), and section 252.153(b)(2) of Regulation YY (12 CFR

252.153(b)(2)). The obligation of covered HCs to report this information is mandatory. In general, the Board does not consider the financial data in these

reports to be confidential. However, a respondent may request confidential treatment pursuant to sections (b)(4), (b)(6), and (b)(8) of the Freedom of Information Act (5 U.S.C. 552(b)(4), (b)(6), and (b)(8)). The applicability of these exemptions would need to be reviewed on a case by case basis.

Board of Governors of the Federal Reserve System, December 27, 2017.

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2017-28290 Filed 12-29-17; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0809]

#### Issuance of Priority Review Voucher; Rare Pediatric Disease Product

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that LUXTURNA (voretigene neparvovec), manufactured by Spark Therapeutics, Inc., meets the criteria for a priority review voucher.

**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:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria upon approval of those applications. FDA has determined that LUXTURNA (voretigene neparvovec), manufactured by Spark Therapeutics, Inc., meets the

criteria for a priority review voucher. LUXTURNA (voretigene neparvovec) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about LUXTURNA (voretigene neparvovec), go to the Center for Biologics Evaluation and Research cellular and gene therapy products website at <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/default.htm>.

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-28256 Filed 12-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-6928]

#### Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comments.

**DATES:** The meeting will be held on March 23, 2018, from 8:30 a.m. to 3:05 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due

to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this document. The docket number is Docket No. FDA-2017-N-6928. The docket will close on March 26, 2018. Submit either electronic or written comments on this public meeting by that date. Please note that late, untimely comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 26, 2018. 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.

Comments received on or before March 9, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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. 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 make 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-2017-N-6928 for "Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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." FDA 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:

Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240-402-3838, [marieann.brill@fda.hhs.gov](mailto:marieann.brill@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>. Scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

#### SUPPLEMENTARY INFORMATION:

**Agenda:** The PAC will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108-155). Comments about the upcoming advisory committee meeting should be submitted to Docket No. FDA-2017-N-6928.

The PAC will meet to discuss the following products (listed by FDA Center):

- (1) Center for Drug Evaluation and Research
  - a. BANZEL
  - b. INTUNIV
  - c. LEXAPRO
- (2) Center for Devices and Radiological Health
  - a. FLOURISH (Humanitarian Device Exemption (HDE))
  - b. ACTIVA (HDE)
  - c. LIPOSORBER (HDE)
  - d. IMPELLA RP SYSTEM

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views,

orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 16, 2018. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 8, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 9, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Marieann Brill at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-28259 Filed 12-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-6753]

#### Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice, establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on February 14, 2018, from 8 a.m. to 12:30 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2017-N-6753. The docket will close on February 13, 2018. Submit either electronic or written comments on this public meeting by February 13, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 13, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 13, 2018. 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.

Comments received on or before January 31, 2018, will be provided to the committees. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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. 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-2017-N-6753 for "Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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