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 Opper, 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