

reports that detail funding vulnerabilities.

Legal authorization and confidentiality: The Board's Legal Division has determined that the FR 2052a is authorized pursuant to section 5 of the Bank Holding Company Act (12 U.S.C. 1844), section 8 of the International Banking Act (12 U.S.C. 3106), and section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) (12 U.S.C. 5365) and are mandatory. Section 5(c) of the Bank Holding Company Act authorizes the Board to require BHCs to submit reports to the Board regarding their financial condition. Section 8(a) of the International Banking Act subjects FBOs to the provisions of the Bank Holding Company Act. Section 165 of the Dodd-Frank Act requires the Board to establish prudential standards for certain BHCs and FBOs, which include liquidity requirements.

Financial institution information required by the FR 2052a is collected as part of the Board's supervisory process. Therefore, such information is entitled to confidential treatment under Exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). In addition, the institution information provided by each respondent would not be otherwise available to the public and its disclosure could cause substantial competitive harm. Accordingly, it is entitled to confidential treatment under the authority of exemption 4 of the FOIA (5 U.S.C. 552(b)(4)), which protects from disclosure trade secrets and commercial or financial information.

Current Actions: The Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), enacted on May 24, 2018, amended various provisions of banking law to eliminate or reduce statutory and regulatory requirements on certain banking organizations. Section 403 of EGRRCPA provides that the federal banking agencies shall treat certain municipal obligations as "high quality liquid assets" (HQLA) for purposes of their liquidity regulations, and must amend those regulations to reflect this new treatment within 90 days of the enactment of EGRRCPA. The federal banking agencies, on August 22, 2018, issued an interim final rule¹ amending their liquidity regulations (the "Liquidity IFR"). The current FR 2052a instructions are inconsistent with the

provisions of EGRRCPA. The Board has revised the FR 2052a to provide that respondents are permitted to report investment grade municipal obligations as HQLA, consistent with EGRRCPA and the Liquidity IFR. In order for the FR 2052a to reflect section 403 of EGRRCPA, which became effective immediately when EGRRCPA was signed on May 24, 2018, the Board cannot comply with the normal clearance process and still receive the June 30, 2018, financial data in a timely manner. Therefore, the Board has determined that the revision to the FR 2052a described above must be instituted quickly and public participation in the approval process would substantially interfere with the Board's ability to perform its statutory obligations arising from EGRRCPA.

Board of Governors of the Federal Reserve System, September 6, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

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FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Board Meeting; 77 K St. NE, Washington, DC; 10th Floor; September 17, 2018; 8:30 a.m.

Open Session

1. Approval of the Minutes of the August 27, 2018 Board Meeting
2. Monthly Reports
 - (a) Participant Activity
 - (b) Investment Policy
 - (c) Legislative Report
3. FY 19 Budget Review and Approval
4. Vendor Risk Management Update
5. Capital Market and L Fund Update
6. IT Update

Closed Session

Information covered under 5 U.S.C. 552b(c)(4) and (c)(9)(B).

CONTACT PERSON FOR MORE INFORMATION:

Kimberly Weaver, Director, Office of External Affairs, (202) 942-1640.

Dated: September 7, 2018.

Dharmesh Vashee,

Deputy General Counsel, Federal Retirement Thrift Investment Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0908]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 12, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to aira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0581. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

OMB Control Number 0910-0581—Extension

Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (21 CFR 312.50 and 312.56 for drugs and biologics, and 21 CFR 812.40 and 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One

¹ Press Release, Board of Governors of the Federal Reserve System, Agencies issue final rule regarding the treatment of certain municipal securities as high-quality liquid assets (August 22, 2018), available at <https://www.federalreserve.gov/newsevents/pressreleases/bcreg20180822a.htm>.