

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 rule<sup>1</sup> 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.*

[FR Doc. 2018-19675 Filed 9-11-18; 8:45 am]

**BILLING CODE 6210-01-P**

## 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.*

[FR Doc. 2018-19833 Filed 9-11-18; 8:45 am]

**BILLING CODE 6760-01-P**

## 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](mailto: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](mailto: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

<sup>1</sup> 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>.

such group is a data monitoring committee (DMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of current trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The guidance document referenced in this document is intended to assist sponsors of clinical trials in determining when a DMC is needed for monitoring a study and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs and describes certain reporting and recordkeeping responsibilities, including the following: (1) Sponsor reporting to FDA on DMC recommendations related to safety; (2) standard operating procedures (SOPs) for DMCs; (3) DMC meeting records; (4) sponsor notification to the DMC regarding waivers; and (5) DMC reports based on meeting minutes to the sponsor.

### **1. Sponsor Reporting to FDA on DMC Recommendations Related to Safety**

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (§ 312.32(c) (21 CFR 312.32(c))) would not apply when the DMC recommendation is related to an excess of events not classifiable as serious. Nevertheless, the Agency recommends in the guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of "serious."

### **2. SOPs for DMCs**

In the guidance, FDA recommends that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;
- Ensure that those with serious conflicts of interest are not included in the DMC;
- Provide disclosure to all DMC members of any potential conflicts that are not thought to impede objectivity and, thus, would not preclude service on the DMC;
- Identify and disclose any concurrent service of any DMC member on other DMCs of the same, related, or competing products;

- Ensure separation, and designate a different statistician to advise on the management of the trial, if the primary trial statistician takes on the responsibility for interim analysis and reporting to the DMC; and

- Minimize the risks of bias that are associated with an arrangement under which the primary trial statistician takes on the responsibility for interim analysis and reporting to the DMC, if it appears infeasible or highly impractical for any other statistician to take over responsibilities related to trial management.

### **3. DMC Meeting Records**

The Agency recommends in the guidance that the DMC or the group preparing the interim reports to the DMC maintain all meeting records. This information should be submitted to FDA with the clinical study report (21 CFR 314.50(d)(5)(ii)).

### **4. Sponsor Notification to the DMC Regarding Waivers**

The sponsor must report to FDA certain serious and unexpected adverse events in drugs and biologics trials (§ 312.32) and unanticipated adverse device effects in the case of device trials (21 CFR 812.150(b)(1)). The Agency recommends in the guidance that sponsors notify DMCs about any waivers granted by FDA for expedited reporting of certain serious events.

### **5. DMC Reports of Meeting Minutes to the Sponsor**

The Agency recommends in the guidance that DMCs should issue a written report to the sponsor based on the DMC meeting minutes. Reports to the sponsor should include only those data generally available to the sponsor. The sponsor may convey the relevant information in this report to other interested parties, such as study investigators. Meeting minutes or other information that include discussion of confidential data would not be provided to the sponsor.

*Description of the Respondents:* The submission and data collection recommendations described in this document affect sponsors of clinical trials and DMCs.

*Burden Estimate:* Table 1 of this document provides the burden estimate of the annual reporting burden for the information to be submitted in accordance with the guidance. Table 2 of this document provides the burden estimate of the annual recordkeeping burden for the information to be maintained in accordance with the guidance. Table 3 of this document provides the burden estimate of the

annual third-party disclosure burden for the information to be submitted in accordance with the guidance.

*Reporting, Recordkeeping, and Third-Party Disclosure Burdens:* Based on information from FDA review divisions, FDA estimates there are approximately 740 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 370 clinical trials. Because FDA has no information on which to project a change in the use of DMCs, FDA estimates that the number of clinical trials with DMCs will not change significantly. For purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 37 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. FDA receives very few requests for waivers regarding expedited reporting of certain serious events; therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial.

The "Average Burden per Response" and "Average Burden per Recordkeeping" are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The "Average Burden per Response" includes the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC, FDA, or the sponsor. The "Average Burden per Recordkeeping" includes the time to record, gather, and maintain the information.

The information collection provisions in the guidance for 21 CFR 312.30,

312.32, 312.38, 312.55, and 312.56 have been approved under OMB control number 0910–0014; 21 CFR 314.50 has been approved under OMB control number 0910–0001; and 21 CFR 812.35

and 812.150 have been approved under OMB control number 0910–0078.

In the **Federal Register** of May 31, 2018 (83 FR 25015), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Section of guidance/reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
5. Sponsor reporting to FDA on DMC recommendations related to safety.	37	1	37	0.50 (30 minutes) ..	18.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Section of guidance/recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual responses	Average burden per recordkeeping	Total hours
4.1. and 6.4 SOPs for DMCs .....	37	1	37	8	296
4.4.3.2. DMC meeting records .....	370	1	370	2	740
Total .....					1,036

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Section of guidance/disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.4.1.2. Sponsor notification to the DMC regarding waivers.	1	1	1	0.25 (15 minutes) ...	0.25
4.4.3.2. DMC reports of meeting minutes to the sponsor.	370	2	740	1 .....	740
Total .....					740.25

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: September 6, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–19799 Filed 9–11–18; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–1960]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program**

**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 [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0291 and title “MedWatch: The Food and Drug Administration Medical Products Reporting Program.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRASStaff@fda.hhs.gov](mailto: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.

**MedWatch: The FDA Medical Products Reporting Program**

*OMB Control Number 0910–0291—Revision*

This information collection supports FDA’s MedWatch safety information and adverse event reporting program. Members of the public use FDA’s MedWatch system to report adverse events, product problems, errors with the use of a human medical product, or when evidence of therapeutic failure is suspected or identified in clinical use.