

the board, senior management, and others within the firm. The frequency of reporting should depend on needs of the firm and the materiality of the issues. Risk reporting should adapt to market downturns or stress events.

### C. Internal Controls

*Principle: A firm should identify its system of internal control and demonstrate that it is commensurate with the firm's size, scope of operations, activities, risk profile, strategy, and risk tolerance, and consistent with all applicable laws and regulations, including those related to consumer protection.*

Internal controls cover a wide range of activities and processes, and could include the following:<sup>52</sup>

- Policies and procedures that set expectations for and govern the firm's business activities and support functions; establish appropriate levels of authority, responsibility, and accountability for overseeing and executing the firm's activities; and establish standards for prudent risk-taking behaviors.
- Clear assignment of roles and responsibilities and appropriate separation of duties.
- Physical controls for restricting access to tangible assets.
- Approvals and appropriate dual authorizations for key decisions, transactions, and execution of processes.
- Verifications of transaction details and periodic reconciliations, such as those comparing cash flows to account records and statements.
- Access controls, change management controls, data entry and related controls.
- Escalation procedures with a system of checks and balances in situations that allow for managerial or employee discretion.

Internal controls instill confidence in financial reporting and are important to ensure the integrity of the process and information relied upon by the firm to manage itself. Developing and maintaining an effective system of internal control is the responsibility of several parties, including business line management.<sup>53</sup> Accordingly, a firm should assign management responsibilities for the establishment and maintenance of internal controls. To foster an appropriate control culture

within the firm, adequate control activities should be integrated into the daily functions of all relevant personnel. All personnel should fully understand and adhere to policies and procedures affecting their duties and responsibilities.

*Principle: A firm should regularly evaluate and test the effectiveness of internal controls, and monitor functioning of controls so that deficiencies are identified and communicated in a timely manner.*

A firm should have mechanisms to test its system of internal control and to identify and escalate issues that appear to compromise its effectiveness. A firm should regularly evaluate and test the quality, reliability and effectiveness of internal controls, and monitor any potential deterioration. Generally, testing activities are conducted at specific points in time, whereas monitoring activities are continuous processes. The scope, frequency, and depth of testing should consider the complexity of the firm, the results of the firm's risk assessments, and the number and significance of the deficiencies identified during prior testing. A firm should test and monitor internal controls using a risk-based approach, prioritizing efforts on controls in areas of highest risk and less effective controls.

A firm should evaluate and communicate internal control deficiencies in a timely manner to those parties responsible for taking corrective action, including senior management. Firms should establish management information systems that track internal control weaknesses and escalate serious matters to the board, senior management, and responsible business line management, as appropriate.

### D. Internal Audit

*Principle: The internal audit function should examine, evaluate, and perform independent assessments of the firm's risk management and internal control systems and report findings to senior management and the firm's audit committee.*

An effective internal audit function provides independent assurance to the board and senior management concerning the effectiveness of risk management and internal control systems. The Federal Reserve issued guidance outlining the key components of an effective internal audit function in SR letter 03-5, and followed that with supplemental guidance in SR letter 13-1/CA letter 13-1, "Supplemental Policy Statement on the Internal Audit Function and Its Outsourcing." The

supplemental guidance builds upon the 2003 interagency guidance of SR letter 03-5 and further addresses the characteristics, governance, and operational effectiveness of a firm's internal audit function. That existing audit guidance remains in place and is not superseded by this guidance.

By order of the Board of Governors of the Federal Reserve System, January 5, 2018.

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2018-00294 Filed 1-10-18; 8:45 am]

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## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 6, 2018.

*A. Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Emmetsburg Bank Shares Inc., Emmetsburg, Iowa*; to acquire 100 percent of the outstanding shares of Panora State Bank, Panora, Iowa.

<sup>52</sup> See SR letter 03-5, "Amended Interagency Guidance on the Internal Audit Function and its Outsourcing."

<sup>53</sup> As described below, the internal audit function should examine, evaluate, and perform an independent assessment of the firm's internal control system.

Board of Governors of the Federal Reserve System, January 8, 2018.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2018-00341 Filed 1-10-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0275]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions

**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 February 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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0616. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [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.

#### Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

OMB Control Number 0910-0616—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and already approved by OMB. The OMB control numbers and expiration dates for those applications and submissions are: 21 CFR parts 312 and 314 (human drugs), OMB control number 0910-0014, expiring February 28, 2019, and OMB control number 0910-0001, expiring December 31, 2017; 21 CFR parts 312 and 601 (biological products), OMB control number 0910-0014, expiring February 28, 2019, and OMB control number 0910-0338, expiring March 31, 2020; and 21 CFR parts 807 and 814 (devices), OMB control number 0910-0120, expiring June 30, 2020, and OMB control number 0910-0231, expiring March 31, 2020.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) amended the PHS Act by adding section 402(j). The provisions broadened the scope of clinical trials subject to submitting information and required additional information to be submitted to the clinical trials databank (<https://clinicaltrials.gov>) (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website after this document publishes in the **Federal Register**) previously established by the National Institutes of Health (NIH)/National Library of Medicine. This includes expanded information on applicable clinical trials and summary information on the results of certain clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form

FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers that are assigned upon submission of required information to the NIH databank at <https://clinicaltrials.gov>.

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement. The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results databank, and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification, are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties. The Form FDA 3674 provides a convenient mechanism for sponsors/applicants/submitters to satisfy the certification requirements of the statutory provision.

To assist sponsors/applicants/submitters in understanding the statutory requirements associated with Form FDA 3674, we have provided a guidance available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm>. This guidance recommends the applications and submissions FDA considers should be accompanied by the certification form, Form FDA 3674. The applications and submissions identified in the guidance are reflected in the burden analysis. In 2017, we updated the guidance to include references to the NIH Final Rule implementing 402(j) of the PHS Act (42 U.S.C. 282(j)). The final rule, published on September 21, 2016 (81 FR 64982) (42 CFR part 11), clarifies the requirements for submission of clinical trial information to <https://clinicaltrials.gov>.

**Investigational New Drug Applications.** FDA's Center for Drug Evaluation and Research (CDER) received 1,669 investigational new drug applications (INDs) and 15,285 clinical protocol IND amendments in calendar year (CY) 2016. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 381 new