

**FEDERAL RESERVE SYSTEM****Government in the Sunshine Meeting Notice**

**AGENCY HOLDING THE MEETING:** Board of Governors of the Federal Reserve System.

**TIME AND DATE:** 10:30 a.m. on Wednesday, October 31, 2018.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, 20th Street entrance between Constitution Avenue and C Streets, NW, Washington, DC 20551.

**STATUS:** Open.

On the day of the meeting, you will be able to view the meeting via webcast from a link available on the Board's public website. *You do not need to register to view the webcast of the meeting.* A link to the meeting documentation will also be available approximately 20 minutes before the start of the meeting. Both links may be accessed from the Board's public website at [www.federalreserve.gov](http://www.federalreserve.gov).

*If you plan to attend the open meeting in person*, we ask that you notify us in advance and provide your name, date of birth, and social security number (SSN) or passport number. You may provide this information by calling 202-452-2474 or you may *register online*. You may pre-register until close of business on Tuesday, October 30, 2018. You also will be asked to provide identifying information, including a photo ID, before being admitted to the Board meeting. The Public Affairs Office must approve the use of cameras; please call 202-452-2955 for further information. If you need an accommodation for a disability, please contact Penelope Beattie on 202-452-3982. For the hearing impaired only, please use the Telecommunication Device for the Deaf (TDD) on 202-263-4869.

**Privacy Act Notice:** The information you provide will be used to assist us in prescreening you to ensure the security of the Board's premises and personnel. In order to do this, we may disclose your information consistent with the routine uses listed in the Privacy Act Notice for BGFRS-32, including to appropriate federal, state, local, or foreign agencies where disclosure is reasonably necessary to determine whether you pose a security risk or where the security or confidentiality of your information has been compromised. We are authorized to collect your information by 12 U.S.C 243 and 248, and Executive Order 9397. In accordance with Executive Order 9397, we collect your SSN so that we can keep accurate records, because other

people may have the same name and birth date. In addition, we use your SSN when we make requests for information about you from law enforcement and other regulatory agency databases. Furnishing the information requested is voluntary; however, your failure to provide any of the information requested may result in disapproval of your request for access to the Board's premises. You may be subject to a fine or imprisonment under 18 U.S.C 1001 for any false statements you make in your request to enter the Board's premises.

**Matters To Be Considered***Discussion Agenda:*

1. Prudential Standards for Large Bank Holding Companies, Savings and Loan Holding Companies, and State Member Banks.

Notes: 1. The staff memos to the Board will be made available to attendees on the day of the meeting in paper and the background material will be made available on a compact disc (CD). If you require a paper copy of the entire document, please call Penelope Beattie on 202-452-3982. The documentation will not be available to the public until about 20 minutes before the start of the meeting.

2. This meeting will be recorded for the benefit of those unable to attend. The webcast recording and a transcript of the meeting will be available after the meeting on the Board's public website <http://www.federalreserve.gov/aboutthefed/boardmeetings/> or if you prefer, a CD recording of the meeting will be available for listening in the Board's Freedom of Information Office, and copies can be ordered for \$4 per disc by calling 202-452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

For more information please contact: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202-452-2955.

**SUPPLEMENTARY INFORMATION:** You may access the Board's public website at [www.federalreserve.gov](http://www.federalreserve.gov) for an electronic announcement. (The website also includes procedural and other information about the open meeting.)

Dated: October 24, 2018

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2018-23559 Filed 10-24-18; 4:15 pm]

**BILLING CODE 6210-01-P**

**FEDERAL RESERVE SYSTEM****Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 13, 2018.

*A. Federal Reserve Bank of Minneapolis* (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Lance E. Skov, Albert Lea, Minnesota*; to become trustee of the Lake Bank Shares, Inc., Employee Stock Ownership Plan, and thereby indirectly acquire shares of Lake Bank Shares, Inc., which owns Security Bank Minnesota, both of Albert Lea, Minnesota.

Board of Governors of the Federal Reserve System, October 22, 2018.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2018-23385 Filed 10-25-18; 8:45 am]

**BILLING CODE 6210-01-P**

**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 November 23, 2018.

*A. Federal Reserve Bank of Boston* (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210-2204. Comments can also be sent electronically to [BOS.SRC.Applications.Comments@bos.frb.org](mailto:BOS.SRC.Applications.Comments@bos.frb.org):

1. *Hometown Financial Group, MHC and Hometown Financial Group, Inc., both of Easthampton, Massachusetts*; to merge with Pilgrim Bancshares, Inc., and thereby acquire Pilgrim Bank, both of Cohasset, Massachusetts.

Board of Governors of the Federal Reserve System, October 23, 2018.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2018-23449 Filed 10-25-18; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-3614]

#### **Biopharmaceuticals Classification System-Based Biowaivers; International Council for Harmonisation; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Biopharmaceuticals Classification System-Based Biowaivers.” The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance will provide recommendations to support

the biopharmaceuticals classification of drug substances and the Biopharmaceuticals Classification System (BCS)-based waiver of in vivo bioequivalence (BE) studies for drug products. In vivo BE studies are needed to demonstrate lack of impact of significant formulation changes on a drug’s bioavailability during its development, for post-approval line extensions, and when developing a generic product. Utilizing the critical properties of the drug substance and the drug product, and applying the BCS framework, assurance of in vivo BE findings can be obtained using extensive in vitro studies. The draft guidance is intended to avoid unnecessary human BE trials based on extensive in vitro characterization of the drug substance and drug product properties.

**DATES:** Submit either electronic or written comments on the draft guidance by January 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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-2018-D-3614 for “Biopharmaceuticals Classification System-Based Biowaivers.” Received comments 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.” The Agency 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.