

For regulatory reporting purposes, the Board is proposing similar treatment for last-of-layer FVHBAs on FR Y-9C Schedule HC-C, Loans and Lease Financing Receivables, and Schedule HC-B, Securities. As such, following the FASB's adoption of a final last-of-layer hedge accounting standard, the instructions for Schedule HC-C, item 11, "LESS: Any unearned income on loans reflected in items 1-9 above," would be revised to explicitly state that last-of-layer FVHBAs associated with the loans reported in Schedule HC-C, should be included in this item.

In addition, the Board is proposing on Schedule HC-B, Securities, to rename existing item 7, "Investments in mutual funds and other equity securities with readily determinable fair values," as "Unallocated last-of-layer fair value hedge basis adjustments." HCs would report amounts for last-of-layer FVHBAs on AFS debt securities only in item 7, column C, "Available-for-sale: Amortized Cost." Only a small number of HCs that have not yet adopted ASU 2016-01, which includes provisions governing the accounting for investments in equity securities, continue to report amounts in item 7. Because all institutions are required to adopt ASU 2016-01 for FR Y-9C purposes by the December 31, 2020, report date, the Board had previously determined that existing item 7 in Schedule HC-B would no longer be applicable to institutions for reporting purposes and could be removed as of that report date.<sup>20</sup> For these reasons, the Board is proposing to redesignate existing item 7, column C, on Schedule HC-B, as a new item for reporting unallocated FVHBAs applicable to AFS debt securities following the FASB's adoption of a final last-of-layer hedge accounting standard.

Board of Governors of the Federal Reserve System, October 2, 2020.

**Michele Taylor Fennell,**

*Assistant Secretary of the Board.*

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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

exposure draft or ASU associated with this project has been issued.

<sup>20</sup> See 83 FR 945-946 (January 8, 2018).

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 public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than November 9, 2020.

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

1. *Northwood Financial Services Corporation, Northwood, Iowa*; to acquire Titonka Savings Bank, Titonka, Iowa.

Board of Governors of the Federal Reserve System, October 5, 2020.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-1553]

#### Premenopausal Women With Breast Cancer: Developing Drugs for Treatment; 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 "Premenopausal Women with Breast Cancer: Developing Drugs for Treatment." This draft guidance provides recommendations regarding the inclusion of premenopausal women in breast cancer clinical trials. The guidance is intended to assist stakeholders, including sponsors and institutional review boards, responsible for the development and oversight of clinical trials for breast cancer drugs.

**DATES:** Submit either electronic or written comments on the draft guidance by December 7, 2020 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."