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 have 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.[20] 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.*

[FR Doc. 2020–22275 Filed 10–7–20; 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 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.*

[FR Doc. 2020–22324 Filed 10–7–20; 8:45 am]

**BILLING CODE P**

## 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.''

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

[20] See 83 FR 945–946 (January 8, 2018).

*Instructions:* All submissions received must include the Docket No. FDA–2020–D–1553 for ''Premenopausal Women with Breast Cancer: Developing Drugs for Treatment.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Gao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2135, Silver Spring, MD 20993–0002, 240–402–4683; Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA 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, as defined by serum hormonal levels (including but not limited to follicle-stimulating hormone and estradiol), in breast cancer clinical trials. The issues of fertility and fertility preservation when treating premenopausal women with breast cancer are outside the scope of this draft guidance.

Historically, premenopausal women have been excluded from some trials that have investigated the efficacy of certain drugs that rely upon manipulation of the hormonal axis for the treatment of hormone receptor (HR) positive breast cancer. In some cases, separate studies have been conducted to confirm the benefit in this patient population, which has resulted in delays in the availability of these therapies for premenopausal women with HR-positive breast cancer. Certain groups of drugs such as chemotherapy, immunotherapy, and targeted therapy (which act independent of the hormonal axis) have similar efficacy in pre- and post-menopausal women with breast cancer. Based on a review of the literature, FDA believes hormonal drugs administered to premenopausal women with HR-positive breast cancer, with adequate estrogen suppression, are likely to have generally the same efficacy and safety profile as in postmenopausal women. The inclusion of premenopausal women in breast cancer oncology product development programs will result in more complete clinical information to inform clinical decision making and bring safe and effective therapies in a timely manner to this patient population.

The draft guidance encourages sponsors to discuss their breast cancer drug development plan with CDER and CBER, as applicable, early in development. The draft guidance recommends that menopausal status not be the basis for exclusion from any breast cancer clinical trial. The draft guidance includes recommendations regarding eligibility criteria and study planning and design intended to facilitate the inclusion of premenopausal women in breast cancer clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Premenopausal Women with Breast Cancer: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-*

*biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: October 2, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–22228 Filed 10–7–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Senior Executive Service Performance Review Board

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA, an operating division of HHS, is publishing a list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members within HRSA for the Fiscal Year 2021 and 2022 review period.

**FOR FURTHER INFORMATION CONTACT:** Georgia Lyons, HRSA, Executive Resources, Office of Human Resources, 5600 Fishers Lane, Rm 12N06C, Rockville, Maryland 20857, or (301) 443–4618.

**SUPPLEMENTARY INFORMATION:** Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons may be named to serve on the HRSA Performance Review Board:

Onyekachukwu Anaedozie
Leslie Atkinson
Cynthia Baugh
Tonya Bowers
Adriane Burton
Tina Cheatham
Laura Cheever
Natasha Coulouris
Cheryl Dammons
Elizabeth DeVoss
Diana Espinosa
Catherine Ganey
Alexandra Garcia
Heather Hauck
Laura Kavanagh
Martin Kramer
Torey Mack
James Macrae
Susan Monarez
Thomas Morris
Luis Padilla
Wendy Ponton
Michael Warren

**Thomas J. Engels,**

*Administrator.*

[FR Doc. 2020–22276 Filed 10–7–20; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Meeting on the Advisory Commission on Childhood Vaccines; Correction

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice; correction.

**SUMMARY:** The original **Federal Register** Notice announcing the December 2020 Advisory Commission on Childhood Vaccines (ACCV) meeting indicated that this meeting would be held on December 3, 2020, and December 4, 2020. This meeting is not being conducted over two days, and instead will only take place on December 3, 2020.

**FOR FURTHER INFORMATION CONTACT:** Annie Herzog, Program Analyst, Division of Injury Compensation Programs (DICP), HRSA, in one of three ways: (1) Send a request to the following address: Annie Herzog, Program Analyst, DICP, HRSA, 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; (2) call (301) 443–6593; or (3) send an email to *ACCV@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** The ACCV will hold a public meeting on December 3, 2020, at 10:00 a.m. Eastern Time. The meeting will be held via Adobe Connect and telephone conference. The public can join the meeting by:

1. (Audio Portion) Calling the conference phone number 888–790–1734 and providing the following information:

*Leader Name:* Ms. Tamara Overby.

*Passcode:* 4177683.

2. (Visual Portion) Connecting to the ACCV Adobe Connect Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/.* Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.*

Meeting times could change. For the latest information regarding the meeting, including start time and the agenda, please access the ACCV website: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.*

*This meeting will only take place on December 3, 2020, and is not being conducted over 2 days (December 3–4, 2020), as stated previously in* ***Federal Register*** *notice 2019–28294 (85 FR 112, published on January 2, 2020, page 112–113).*

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2020–22209 Filed 10–7–20; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; 60-Day Comment Request; Cancer Therapy Evaluation Program (CTEP) Branch and Support Contracts Forms and Surveys (National Cancer Institute)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michael Montello, Pharm. D., Cancer Therapy Evaluation Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240–276–6080 or email your request, including your address to: *montellom@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written