2. Activity-Based Stock Purchase Requirement Submissions

FHFA estimates that the average number of daily transactions between Banks and members that will require the exchange of information to confirm the member's activity-based stock purchase requirement will be 300, and that there will be an average of 261 working days per year, resulting in an estimated 78,300 submissions annually. The estimate for the average preparation time per submission is 0.2 hours. Accordingly, the estimate for the annual hour burden associated with activity-based stock purchase requirement submissions is (78,300 submissions × 0.2 hours per submission) = 15,660 hours.

E. Comment Request

In accordance with the requirements of 5 CFR 1320.8(d), FHFA published an initial notice and request for public comments regarding this information collection in the **Federal Register** on August 8, 2023.[4] The 60-day comment period closed on October 10, 2023. FHFA received no substantive comments.

FHFA requests written comments on the following: (1) whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Shawn Bucholtz,

Chief Data Officer, Federal Housing Finance Agency.

[FR Doc. 2023–23067 Filed 10–18–23; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL RESERVE SYSTEM

Sunshine Meeting Notice

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

TIME AND DATE: 1:00 p.m. on Wednesday, October 25, 2023.

PLACE: Martin Federal Reserve Board Building, C Street entrance between 20th and 21st 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 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 website at *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 *www.federalreserve.gov*. You may pre-register until close of business on October 24, 2023. 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 email *media@frb.gov* for further information. If you need an accommodation for a disability, please contact Penelope Beattie on 202–452–3982. For users of telephone systems via text telephone (TTY) or any TTY-based Telecommunications Relay Services (TRS), please call 202–263–4869 or dial 7–1–1 from any telephone, anywhere in the United States.

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. Proposed revisions to the Board's debit interchange fee cap.

Notes: 1. For those attending in person, the staff memo will be available to attendees on the day of the meeting in paper. Meeting documentation will be available on the Board's website 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 website *http://www.federalreserve.gov/aboutthefed/boardmeetings/*.

For questions please contact: Public Affairs Office at *media@frb.gov*.

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

Dated: October 16, 2023.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2023–23116 Filed 10–18–23; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4356]

Enforcement Policy for Non-Invasive Remote Monitoring Devices Used To Support Patient Monitoring; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring.'' The enforcement policy described in this guidance applies to modified devices where the original device was a legally marketed, non-invasive remote monitoring device listed in the guidance that measures or detects common physiological parameters and that is used to support patient monitoring. The guidance is intended to describe the enforcement policy for limited modifications to the indications, functionality, or hardware

[4] *See* 88 FR 53484 (Aug. 8, 2023).

or software of device types in the scope of the guidance without prior submission of a 510(k) where such submission would be required.

DATES: The announcement of the guidance is published in the **Federal Register** on October 19, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2023–D–4356 for ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jessica Paulsen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2108, Silver Spring, MD 20993–0002, 301–796–6883.

SUPPLEMENTARY INFORMATION:

I. Background

The enforcement policy described in this guidance applies to modified devices where the original device was a legally marketed, noninvasive remote monitoring device listed in the guidance that measures or detects common physiological parameters and that is used to support patient monitoring. The guidance is intended to describe the enforcement policy for limited modifications to the indications, functionality, or hardware or software of device types in the scope of the guidance without prior submission of a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) (see 21 CFR 807.81) where such submission would be required. This guidance supersedes ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' issued in March 2020 and updated in June 2020, October 2020, and March 2023.

In the **Federal Register** of March 13, 2023 (88 FR 15417), FDA announced that that guidance was being revised to continue in effect for 180 days after the expiration of the COVID–19 public health emergency (PHE) declaration issued under section 319 of the Public Health Service Act, during which time, FDA intended to further revise the guidance. Consistent with what we said in the **Federal Register** of March 13, 2023, FDA is therefore issuing this revised final guidance.

Leveraging the perspective gained during the COVID–19 pandemic, FDA is updating the policy reflected in the ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' guidance to exercise certain enforcement policies for certain devices beyond the expiration of the COVID–19 PHE (which expired on May 11, 2023) and the 180-day period announced in the March 13, 2023 **Federal Register** notice, including by removing clinical thermometers and pulse oximeters from the scope of the guidance, revising the policy with

respect to certain device types subject to special controls, and removing use of the term ''claims.''

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2) (21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this policy is being implemented immediately without prior comment, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(i)(D)). FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007017 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved 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 the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: October 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23110 Filed 10–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4414]

American Regent, Inc., et al.; Withdrawal of Approval of Eight Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of eight abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 20, 2023.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived the opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040515	Promethazine Hydrochloride Injectable, 25 milligrams (mg)/milliliter (mL).	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 080028	Sulfacetamide Sodium Solution/Drops, 10% and 30%.	Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612.
ANDA 091300	Riluzole Tablet, 50 mg	Apotex Corp., U.S. Agent for Apotex Inc., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326.
ANDA 200271	Hydroxyprogesterone Caproate Solution, 1,250 mg/5 mL (250 mg/mL).	Lachman Consultant Services, Inc., U.S. Agent for Aspen Global Inc., 1600 Stewart Ave., Suite 604, Westbury, NY 11590.
ANDA 201570	Abacavir Sulfate Tablet, Equivalent to (EQ) 300 mg base.	Apotex Corp., U.S. Agent for Apotex Inc.