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.

Application No.	Drug	Applicant
ANDA 202784	Esomeprazole Magnesium Capsule, Delayed Release Pellets, EQ 20 mg base and EQ 40 mg base.	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd., Unit-III, 1035 Centennial Ave., Piscataway, NJ 08854.
ANDA 208413	Choline C–11 Injectable, 4–33.1 millicurie/mL	Washington University School of Medicine, 510 South Kingshighway Blvd., St. Louis, MO 63110.
ANDA 208939	Esomeprazole Magnesium Capsule, Delayed Release, EQ 20 mg base.	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 20, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved new drug application or abbreviated new drug application violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on November 20, 2023 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23064 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–1005]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups and Interviews as Used by the Food and Drug Administration

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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by November 20, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0497. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@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.

Focus Groups and Interviews as Used by the Food and Drug Administration

OMB Control No. 0910–0497—Extension

FDA conducts focus groups and in-depth individual interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco products, and veterinary medicine.

Focus groups are an important role in gathering information because they allow for a better understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies and encourages interaction between participants.

Individual interviews allow for a more comprehensive, in-depth information exchange where more insights are likely to be collected.

Both focus groups and in-depth individual interviews serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use findings to test and refine ideas but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies.

Respondents to this collection of information will include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic.

In the **Federal Register** of April 11, 2023 (88 FR 21680), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, two in support of the information collection, and one that did not address the elements of the PRA.

FDA estimates the burden of this collection of information as follows: