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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 20, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table.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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups and individual in-depth interviews	12,000	1	12,000	1.75	21,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden for the information collection reflects an overall increase of 5,600 hours and a corresponding increase of 3,200 responses. We have added individual in-depth interviews as a method of information gathering. In addition, we are consolidating ICR 0910–0677, ''Focus Groups About Drug Products as Used by the Food and Drug Administration'' into this request for extension.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23011 Filed 10–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1057 and FDA–2020–D–1136]

Food and Drug Administration; Center of Drug Evaluation and Research Guidance Documents Related to Coronavirus Disease 2019, Expiration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of guidances for industry entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act,'' which posted March 2020 to communicate recommendations for notifying the Agency about the permanent discontinuance or interruption in manufacturing of certain drug products; and ''COVID–19: Potency Assay Consideration for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity'' which posted January 2021 to communicate information on the development of monoclonal antibodies (mAbs) and other therapeutic proteins for use as COVID–19 therapeutics. FDA is withdrawing these two guidance documents because new draft guidances are available that reflect comments received on the COVID–19 guidances, and many of the recommendations set forth in the COVID–19 guidances are applicable outside the context of the public health emergency (PHE) and included in the draft guidances.

DATES: The expiration date is November 7, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2357.

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, the Agency published on the FDA website the guidance for industry entitled ''Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act'' in March 2020, and announced its availability in the **Federal Register** on April 6, 2020 (85 FR 18247), (Notifying FDA Guidance); and in January 2021, the Agency published on the FDA website the guidance for industry entitled ''COVID–19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity'' and announced its availability in the **Federal Register** February 19, 2021 (86 FR 10285), (Potency Assay Guidance). The Notifying FDA Guidance explained that during the COVID–19 pandemic FDA had been closely monitoring the medical supply chain with the expectation that it may be impacted by the COVID–19 outbreak, potentially leading to supply disruptions or shortages of drug and biological products in the United States. The Notifying FDA Guidance, therefore, communicated the Agency's recommendations for providing timely, informative notifications about changes in the production of certain drugs and biological products to help the Agency in its efforts to prevent or mitigate shortages of such products. The Potency Assay Guidance communicated information to assist sponsors in the development of mAbs and other therapeutic proteins for use as COVID–19 therapeutics and described how potency assay methods required for release and stability testing can be shown to assess known or potential mechanism(s) of action of the product. The guidance also described methods that applicants should use to ensure the potency of mAbs and other therapeutic proteins proposed for use in as anti-infective agents for COVID–19. FDA issued both guidances to communicate its recommendations for the duration of the COVID–19 PHE declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). We also said in both guidances that we expected their recommendations would continue to apply in circumstances outside the context of the PHE and that following the end of the COVID–19 PHE, FDA intended to revise and replace the guidances with updated guidances that incorporated any appropriate changes based on comments received and the Agency's experience with implementation. Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the COVID–19-related guidance documents that will no longer be in effect with the expiration of the COVID–19 PHE declaration on May 11, 2023, guidances that FDA revised to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and guidances that FDA revised to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The Notifying FDA Guidance and the Potency Assay Guidance were included in the latter category and were revised to remain in effect for 180 days post expiration of the PHE declaration.

FDA also stated in the **Federal Register** of March 13, 2023, that the

[1] The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19).