- Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine.
- Cheri Lattimer, Executive Director, National Transitions of Care Coalition.
- Cori McMahon, Vice President, Tridiuum.
- Alan Meade, Director of Rehabilitation Services, Holston Medical Group.
- Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated.
- Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska.
- Morgan Reed, Executive Director, Association for Competitive Technology.
- Margot Savoy, Senior Vice President, American Academy of Family Physicians.
- Congresswoman Allyson Schwartz, Senior Advisor, FTI Consulting.
- Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the February 3, 2022 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (September 15, 2021) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-february-3-2022-virtual-meeting-tickets-212590763697* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: January 11, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–00745 Filed 1–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1037]

Fresenius USA, Inc., et al.; Withdrawal of Approval of 216 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of October 22, 2021. The document announced the withdrawal of approval of 216 abbreviated new drug applications (ANDAs) from multiple applicants, as of November 22, 2021. The document was published with an incorrect date. In addition, the document indicated that FDA was withdrawing approval of ANDA 075941, Strontium Chloride SR–89 Injection, 1 millicurie/milliliter, held by Bio-Nucleonics, Inc., 1600 Market St., Suite 13200, Philadelphia, PA 19103, for repeated failure to submit annual reports. Before FDA withdrew the approval of this ANDA, the application holder informed FDA that it submitted annual reports for ANDA 075941. Therefore, FDA rescinds its withdrawal of approval of ANDA 075941. The approval of ANDA 075941 is still in effect.

FOR FURTHER INFORMATION CONTACT: James Hanratty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–4718, *James.Hanratty@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Corrections

In the **Federal Register** of Friday, October 22, 2021 (86 FR 58675), in FR Doc. 2021–23075, the following corrections are made:

1. On page 58675, in the second column, correct the **DATES** section to read: **DATES:** Approval is withdrawn as of October 22, 2021.''

2. On page 58679, in the table, remove the entry for ANDA 075941.

Dated: January 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00831 Filed 1–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0885]

Determination That PEPCID (Famotidine) Tablet, 20 Milligrams and 40 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PEPCID (famotidine) tablet, 20 milligrams (mg) and 40 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring,

MD 20993–0002, 301–796–8363, *stacy.kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PEPCID (famotidine) tablet, 20 mg and 40 mg, is the subject of NDA 019462, held by Valeant Pharmaceuticals North America LLC, and initially approved on October 15, 1986. PEPCID is indicated in adult and pediatric patients 40 kilograms and greater for the treatment of active duodenal ulcer (DU), active gastric ulcer, symptomatic nonerosive gastroesophageal reflux disease (GERD), erosive esophagitis due to GERD, diagnosed by biopsy. PEPCID is indicated in adults for the treatment of pathological hypersecretory conditions (*e.g.,* Zollinger-Ellison syndrome, multiple endocrine neoplasias) and reduction of the risk of DU recurrence.

PEPCID (famotidine) tablet, 20 mg and 40 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Zydus Pharmaceuticals (USA) Inc. submitted a citizen petition dated August 3, 2021 (Docket No. FDA–2021–P–0885), under 21 CFR 10.30, requesting that the Agency determine whether PEPCID (famotidine) tablet, 20 mg and 40 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PEPCID (famotidine) tablet, 20 mg and 40 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PEPCID (famotidine) tablet, 20 mg and 40 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PEPCID (famotidine) tablet, 20 mg and 40 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PEPCID (famotidine) tablet, 20 mg and 40 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00832 Filed 1–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0007]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 17, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Joseph Raborn *joseph.raborn@hhs.gov* or (202) 870–2037. When submitting comments or requesting information, please include the document identifier 4040–0007–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Assurances for Non-Construction Programs (SF–424B).

Type of Collection: Renewal.

OMB No.: 4040–0007.

Abstract: Assurances for Non-Construction Programs (SF–424B) is used by applicants to apply for Federal financial assistance. The Assurances for Non-Construction Programs (SF–424B) form requests that the applicants certify specified required assurances as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2022.