catalogs or other public documents during the normal course of business. The nominal amount of burden imposed on the public is simply to relay the requested information.

Respondents: 14,000.
Responses per Respondent: 1.
Total Annual Responses: 14,000.
Hours per Response: 0.03 (2 minutes).
Total Burden Hours: 420.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division, at *GSARegSec@gsa.gov*.

Please cite OMB Control No. 3090–0250, FSS Contract Administration Information, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2023–24433 Filed 11–3–23; 8:45 am]

BILLING CODE 6820–14–P

GENERAL SERVICES ADMINISTRATION

[Notice-MRB–2023–06; Docket No. 2023–0002; Sequence No. 37]

GSA Acquisition Policy Federal Advisory Committee; Notification of Upcoming Web-Based Public Meeting

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: GSA is providing notice of a meeting of the GSA Acquisition Policy Federal Advisory Committee (hereinafter ''the Committee'' or ''the GAP FAC'') in accordance with the requirements of the Federal Advisory Committee Act (FACA). This meeting will be open to the public, accessible via webcast. Information on attending and providing written public comment is under the **SUPPLEMENTARY INFORMATION** section.

DATES: The GAP FAC will hold an open public meeting on Tuesday, December 5, 2023, from 1 p.m. to 4:30 p.m. eastern standard time (EST).

ADDRESSES: The meeting will be accessible via webcast. Registrants will receive the webcast information before the meeting.

FOR FURTHER INFORMATION CONTACT: Boris Arratia, Designated Federal Officer, OGP, 703–795–0816, or email: *boris.arratia@gsa.gov*; or Stephanie Hardison, OGP, 202–258–6823, or email: *stephanie.hardison@gsa.gov*. Additional information about the Committee, including meeting materials and agendas, are available on-line at *https://gsa.gov/policy-regulations/policy/acquisition-policy/gsa-acquisition-policy-federal-advisory-committee*.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting

The purpose of this meeting is for each of the three subcommittees (Policy and Practice, Industry Partnerships, and Acquisition Workforce) to present recommendations to the full Committee. The Committee will, in turn, deliberate and vote on GAP FAC recommendations to be delivered to the GSA Administrator.

Meeting Agenda

- Opening Remarks
- Guest Speaker
- Acquisition Workforce Subcommittee Recommendations and Discussion
- Vote on recommendations
- Industry Partnerships Subcommittee Recommendations and Discussion
- Vote on recommendations
- Policy and Practices Subcommittee Recommendations and Discussion
- Vote on recommendations
- Closing Remarks and Adjourn

Meeting Registration

This meeting is open to the public and will be accessible by webcast. Registration information is located on the GAP FAC website: *https://www.gsa.gov/policy-regulations/policy/acquisition-policy/gsa-acquisition-policy-federal-advisory-committee*. Public attendees who want to attend virtually will need to register no later than 5 p.m. EST, on Monday, December 4, 2023 to obtain the meeting webcast information. All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive webcast access information details via email.

Public Comments:

Written public comments are being accepted via email at *gapfac@gsa.gov*. To submit a written public comment, please email at *gapfac.gsa.gov* and include your name, organization name (if applicable).

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2023–24432 Filed 11–3–23; 8:45 am]

BILLING CODE 6820–RV–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–2536]

Determination That FORADIL (Formoterol Fumarate) Inhalation Powder, 0.012 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, the Agency, or we) has determined that FORADIL (formoterol fumarate) inhalation powder, 0.012 milligrams (mg)/inhalation (inh), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for formoterol fumarate inhalation powder, 0.012 mg/inh, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Joe Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 202–815–5571, *joseph.thomas1@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.

FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, is the subject of NDA 020831, held by Novartis Pharmaceuticals Corp., and initially approved on February 16, 2001. FORADIL is indicated for treatment of asthma in patients 5 years of age and older as an add-on to a long-term asthma control medication such as an inhaled corticosteroid; prevention of exercise-induced bronchospasm (EIB) in patients 5 years of age and older; and maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease.

In a letter dated September 30, 2015, Novartis Pharmaceuticals Corp. notified FDA that FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of June 21, 2018 (83 FR 28856), FDA announced that it was withdrawing approval of NDA 020831, effective July 23, 2018.

K&L Gates LLP submitted a citizen petition dated June 21, 2023 (Docket No. FDA–2023–P–2536), under 21 CFR 10.30, requesting that the Agency determine whether FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, 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 FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, 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: November 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24506 Filed 11–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Revision of HHS National Environmental Policy Act Compliance Procedures To Incorporate Federal Flood Risk Management Standard Procedures

AGENCY: Assistant Secretary for Administration, U.S. Department of Health and Human Services (HHS).

ACTION: Notice; request for comments.

SUMMARY: HHS is proposing a revision to its floodplain management procedures to include climate science if an action takes place in a floodplain.

DATES: Interested parties should submit written comments to **FOR FURTHER INFORMATION CONTACT** section shown below on or before December 6, 2023 to be considered in the formation of the final procedures.

FOR FURTHER INFORMATION CONTACT: CDR Leo Angelo Gumapas, Environmental Engineering Program Chief, at 202–669–6942 or by email at *leoangelo.gumapas@psc.hhs.gov,* for clarification of content.

SUPPLEMENTARY INFORMATION:

Background

E.O. 13690 of January 30, 2015—*Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input*—was issued to improve the nation's resilience to flooding and to better prepare for the impacts of climate change. In amending and building upon E.O. 11988—*Floodplain Management*—which was issued in 1977, E.O. 13690 and the associated FFRMS reinforce the important tenets and concepts articulated in E.O. 11988, such as avoiding actions in or impacting a floodplain and minimizing potential harm if an action must be located in a floodplain. When avoiding a floodplain is not possible, E.O. 13690 calls for agencies to improve the resilience of communities and federal actions.

On August 15, 2017, E.O. 13807 was issued, which revoked E.O. 13690. Accordingly, the ''Revised Guidelines for Implementing Executive Order 11988, Floodplain Management'' and its supplementary policy were withdrawn. On May 20, 2021, E.O. 14030, reinstated E.O. 13690 and all supplementary policies.

HHS's current floodplain management procedures are published in the General Administration Manual Part 30: Environmental Protection (GAM–30) section 30–40–40 Floodplain Management, and they are based on E.O. 11988. The GAM–30 was last updated on February 25, 2000, and it is based on outdated laws and regulations. Program Support Center (PSC) √ Real Estate, Logistics, Operations (RLO) √ Real Property Management Service (RPMS) √ Real Property Policy and Strategy (RPPS) drafted HHS FFRMS procedures based on E.O. 13690 to update GAM–30 Section 30–40–40 Floodplain Management.

The Council on Environmental Quality (CEQ) reviewed HHS's FFRMS procedures and provided favorable comments on December 2022.

Procedure Revisions

Revised General Administration Manual, HHS Part 30, Environmental Protection

Part 30—Environmental Protection

30–40 Natural Asset Review
30–40–40 Floodplain Management