

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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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10.30, requesting that the Agency determine whether FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was withdrawn from sale for reasons of safety or effectiveness.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time, FDA has determined under § 314.161 that FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was not withdrawn for reasons of safety or effectiveness.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.

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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

Purpose: Executive Order (E.O.) 13690 on Establishing a Federal Flood Risk Management Standard (FFRMS) and a Process for Further Soliciting and Considering Stakeholder Input (2015), establishes a Federal Flood Risk Management Standard to ensure each Federal agency takes actions to enhance the Nation's resilience to current and future flooding and better prepare the United States for the impacts of climate change, such as sea level rise and extreme weather events. E.O. 13690 and the associated FFRMS amended and built upon E.O. 11988 on Floodplain Management (1977), which requires agencies to take action to reduce the risk of flood loss, to minimize the impacts of floods on human safety, health, and welfare, and to restore and preserve the natural and beneficial values served by floodplains. E.O. 13690 modernizes E.O. 11988 by increasing the vertical flood elevation and expanding corresponding horizontal extent of the floodplain to consider changing flood hazards due to climate change and other processes, and by encouraging climate-conscious resilient design if there are no practicable locations outside the expanded floodplain.

Definitions

Base Flood. "Base Flood" means that flood which has a one percent of greater chance of occurrence in any given year.

Base Flood Elevation (BFE). "BFE" means the computed elevation to which the floodwater is anticipated to rise during the base flood.

Base Floodplain. "Floodplain" means the area subject to flooding by the base flood, the flood that has a one percent or greater chance of flooding in any given year.

Climate-Informed Science Approach (CISA). "CISA" means the flood hazard area (vertical flood elevation and corresponding horizontal extent) that results from using the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science.

Critical Action. "Critical Action" means any activity for which even a slight chance of flooding is too great, e.g., elderly housing proposals.

Federal Flood Risk Management Standard (FFRMS). "FFRMS" means the floodplain determined using one of the three approaches: CISA, 0.2PFA, and FVA.

Freeboard Value Approach (FVA). "FVA" means the flood hazard area that results from adding an additional 2 feet to the BFE and expanding to the corresponding horizontal extent for non-critical actions, and by adding an

additional 3 feet to the BFE and expanding to the corresponding horizontal extent for critical actions.

Horizontal Extent. "Horizontal Extent" means the horizontal land area flooded by the vertical extent (extra flood elevation beyond the BFE).

Nature-Based Approach. HHS OPDIVs/STAFFDIVs, where possible, must use natural systems, ecosystem processes, and natural features and nature-based approaches in development of alternatives for proposed action.

Vertical Extent. "Vertical Extent" means the additional flood height above the BFE.

0.2-Percent-Annual-Chance (500-year) Flood Approach (0.2PFA). "0.2PFA" means the area subject to flooding by the 0.2-percent annual chance flood.

Responsibilities: Each OPDIV/STAFFDIV has the responsibility under E.O. 13690 to act on Federally Funded Projects to reduce the risk of flood loss, to minimize the impact of floods on human safety, health, and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for:

- Acquiring, managing, and disposing of Federal lands and facilities
- Providing Federally undertaken, financed, or assisted construction, substantial improvements, and substantial damages to structures and facilities
- Conducting Federal activities and programs affected land use, including but not limited to, water and related land resources planning, regulating, and licensing activities.

Each OPDIV/STAFFDIV shall determine whether the site in which their action would occur could potentially be inundated by floodwaters using FFRMS and shall use this information to make an informed decision to either avoid siting in the determined flood hazard area or design the action to be more resilient to the associated flood hazard. Each OPDIV/STAFFDIV shall evaluate the potential effects of any actions it may take in a FFRMS floodplain in accordance with the floodplain assessment procedures in this section. It must also ensure that its planning programs and budget requests reflect consideration of flood hazards and floodplain management.

Integration with NEPA. OPDIVs/STAFFDIVs are to evaluate the potential effects of a proposed action in a floodplain in accordance with the procedures for National Environmental Policy Act (NEPA) review in HHS General Administration Manual Part 30–50. If an environmental assessment

(EA) or environmental impact statement (EIS) is required to be prepared for the proposed action, a floodplain assessment as described Paragraph E of this section, shall be included in the EA or EIS.

Floodplain Assessment (E.O. 13690)

Determine if Proposed Action is in a FFRMS floodplain: First, determine if Federally Funded Project is a critical action, which impacts floodplain determinations for the FVA approach. Second, evaluate the vertical extent and corresponding horizontal extent to establish the FFRMS floodplain using one of the three approaches in the following is the order of preference pending data availability:

CISA

0.2PFA

FVA

Involve Public in Decision-making

Process: Notify the public such as a notice in a local newspaper or posting in an accessible public space for the area where the action is under consideration. Public notifications and all supporting communications and activities should be accessible to all (e.g., plain language, culturally responsive, and accommodating), including but not limited to those with disabilities or limited English proficiency. All public notifications are required to follow all guidance and regulation regarding 508 compliance, the use of plain language, and limited English proficiency. If completing an EA or EIS, then include floodplain notice in Description of Proposed Action and Alternatives or Notice of Intent, respectively.

Identify and Evaluate Practicable Alternatives to Locating in FFRMS Floodplain: OPDIVs/STAFFDIVs shall use input from public comments on practicable alternatives, including, if possible, nature-based solutions.

Identify Adverse and Beneficial Impacts: Identify adverse and beneficial impacts, including stimulating floodplain development, which may result from the project. Analyze the following factors: (1) Natural environment (water resources, hydrology, topography, habitat); (2) Social concerns (environmental justice, visual quality/aesthetics, historic and cultural values, land use patterns), (3) Economic Aspects (costs of construction, transportation, relocation, natural features, and ecosystem processes), and (4) Legal considerations (deeds, leases).

Mitigate Adverse Impacts: Minimize impacts identified and restore and preserve the beneficial values served by

floodplains. The analysis shall discuss the following: Alternatives to the proposed action that may avoid adverse effects and incompatible development in the floodplain, including the alternatives of no action or location at an alternate site. Proposed buildings and structures located in FFRMS floodplain shall be programmed and designed to latest version of the American Society of Civil Engineers "Flood Resistant Design and Construction" (ASCE/SEI 24-14) provisions to mitigate the adverse effects of the proposed action.

Senior Real Property Official Approval: No action shall take place involving HHS Federal Real Property in an FFRMS floodplain without a finding by the Senior Real Property Officer that the only practicable alternative consistent with the law and with the policy set forth in E.O. 13690 requires siting in a FFRMS floodplain. The action involving HHS Federal Real Property proposed for Senior Real Property Official approval shall be designed to minimize potential harm to or within the FFRMS floodplain. The Senior Real Property Official shall approve proposed actions requiring an EA or EIS on projects involving HHS Federal Real Property affecting FFRMS floodplains.

Re-Evaluate Alternatives: Use any new information obtained from Public Notice to determine if the proposed project is still applicable. Reissue public notice with Finding of No Significant Impact or Record of Decision if EA or EIS is drafted, respectively.

Announce and Explain Decision to the Public (Notice): Notify the public of the draft decision by publishing such as a notice in a local newspaper or posting in an accessible public space, dating the notice and the posting at removal.

For programs subject to E.O. 12372, the public notice shall be sent to the appropriate state and local reviewing agencies the geographic areas affected. A public review period of 30 days after the issuance of the public notice shall be allotted before any action is taken.

Implement the Proposed Federally Funded Project: Implement the Federally Funded Project with appropriate mitigation measures. Design and construction contracts shall include any mitigation measures are identified through the process. Ensure through independent 3rd party construction quality assurance that mitigation measures are fully implemented.

Licenses, permits, loans, or grants: Each OPDIV/STAFFDIV shall take FFRMS into account when formulating or evaluating any water and land use plans and shall require land and water

resources use appropriate risk management measures to mitigate the degree of hazard involved. Adequate provision shall be made for the evaluation and consideration of flood hazards determined by FFRMS for the licenses, permits, loan, or grant-in-aid programs that an OPDIV/STAFFDIV administers. OPDIVs/STAFFDIVs shall also encourage and provide appropriate guidance to applicants to evaluate the effects of their proposal in FFRMS floodplains prior to submitting applications for Federal licenses, permits, loans, or grants.

Authorization or Appropriation Requests: OPDIVs/STAFFDIVs shall indicate in any requests for new authorizations or appropriations whether the proposed action is in accord with Executive Order 13690 if the proposed action will be in a floodplain.

Guidance: The following resources provides guidance for Implementation of FFRMS. FFRMS Floodplain Determination Job Aid.

Reducing Flood Losses through the International Codes: Coordinating Building Codes and Floodplain Management Regulations, 5th Edition, September 2019

Protecting Building Utility Systems from Flood Damage: Principles and Practices for the Design and Construction of Flood Resistant Building Utility Systems, Federal Emergency Management Agency (FEMA) P-348, Edition 2, February 2017

Cheryl R. Campbell,

Assistant Secretary for Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Institute Environmental Health Sciences, December 03, 2023, 07:00 p.m. to December 05, 2023, 04:45 p.m., NIEHS, Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 which was published in the **Federal Register** on October 05, 2023, 88 FR 69209.

Meeting is being amended to reflect updated agenda.

Name of Committee: Board of Scientific Counselors, National Institute Environmental

Health Sciences ESBSC December 3-5, 2023 Meeting.

Date: December 3-5, 2023.

Closed: December 03, 2023, 7:00 p.m. to 8:00 p.m.

Agenda: Discussion of BSC Reviews.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 8:30 a.m. to 10:00 a.m.

Agenda: Meeting Overview and Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 10:15 a.m. to 11:55 a.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 11:55 a.m. to 12:40 p.m.

Agenda: 1:1 Sessions with Investigators.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 12:40 p.m. to 1:30 p.m.

Agenda: Working Lunch.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 1:35 p.m. to 2:25 p.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 2:25 p.m. to 2:40 p.m.

Agenda: 1:1 Session with Investigator.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 2:55 p.m. to 4:25 p.m.

Agenda: Poster Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 3:30 p.m. to 4:20 p.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive,