https://www.govinfo.gov/content/pkg/FR-2018-10-18/pdf/2018-22697.pdf) and input gained from the public workshop entitled, ''Content of Premarket Submissions for Management of Cybersecurity in Medical devices'' held on January 29–30, 2019.[2] Several changes were made in this draft guidance, including a change in title to better capture the scope of the current draft guidance, document structure change to align with use of a Secure Product Framework, removal of risk tiers, replacement of the Cybersecurity Bill of Materials with Software Bill of Materials, additional clarification regarding premarket submission document requests throughout the draft guidance, and addition of Investigational Device Exemptions to the scope.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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This draft guidance is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1825–R1 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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 or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07614 Filed 4–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0077]

Determination That NASONEX (Mometasone Furoate) Nasal Spray, 0.05 Milligram/Spray (50 Microgram), 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, Agency, or we) has determined that NASONEX (mometasone furoate) nasal spray, 0.05 milligram (mg)/spray (50 microgram (mcg)), 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: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@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).

[2] *https://wayback.archive-it.org/7993/20201222110245/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-content-premarket-submissions-management-cybersecurity-medical-devices-january-29-30.*

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.

NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg), is the subject of NDA 020762, held by Organon LLC, and initially approved on October 1, 1997. NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) is a corticosteroid indicated for:

- Treatment of nasal symptoms of allergic rhinitis in patients 2 years of age and older;
- treatment of nasal congestion associated with seasonal allergic rhinitis in patients 2 years of age or older;
- prophylaxis of seasonal allergic rhinitis in patients 12 years of age or older; and
- treatment of nasal polyps in patients 18 years of age or older.

In a letter dated December 4, 2020, Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., notified FDA that NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Aurobindo Pharma Ltd. submitted a citizen petition dated January 14, 2022 (Docket No. FDA–2022–P–0077), under 21 CFR 10.30, requesting that the Agency determine whether NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg), 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 NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) 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 NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg), 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: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07563 Filed 4–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): 2022 HHS Environmental Justice Strategy and Implementation Plan Draft Outline

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice of request for information.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this Request for Information (RFI) to receive input from the public on HHS' draft outline to further the development of the 2022 Environmental Justice Strategy and Implementation Plan. Consistent with the policy of this administration directing HHS to make achieving environmental justice part of its mission, HHS would like to identify priority actions and strategies to best address environmental injustices and health inequities for people of color, disadvantaged, vulnerable, low-income, marginalized, and indigenous populations. With the engagement of and input from the public, the 2022 Environmental Justice Strategy and Implementation Plan will serve as a guide to confront environmental and health disparities and implement a multifaceted approach that will serve vulnerable populations and communities disproportionately impacted by environmental burdens.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than midnight Eastern Time (ET) on May 19, 2022. HHS will not reply individually to responders but will consider all comments submitted by the deadline. Do not provide confidential information as comments may be published or otherwise used for agency purposes.

ADDRESSES: Please submit all responses via email to *OASHcomments@hhs.gov* as a Word document or in the body of an email.

FOR FURTHER INFORMATION CONTACT: Dr. LaToria Whitehead, Senior Public Health Analyst, *email: ceq6@cdc.gov, phone:* (770) 488–3633.

SUPPLEMENTARY INFORMATION: The mission of the U.S. Department of Health and Human Services is to enhance the health and well-being of Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. For years studies have demonstrated that people of color and disadvantaged, vulnerable, low-income, marginalized, and indigenous populations are disproportionately burdened by environmental hazards.[1] These populations are often exposed to unhealthy land uses, poor air and water quality, dilapidated housing, lead exposure, and other environmental threats that drive health disparities. Many of these communities are underserved and surrounded by social inequities such as job insecurity, underemployment, linguistic isolation, underperforming schools, noise, crowded homes, lack of access to

[1] Toxic Wastes and Race at Twenty 1987—2007. A Report Prepared for the United Church of Christ Justice & Witness Ministries. Principal Authors: Bullard R, Mohai P, Saha R, Wright B. 2007.