Our estimated burden for the information collection reflects an overall increase of 695 hours and a corresponding increase of 12 responses. Based on a review of the information collection since our last request for OMB renewal, the increase in the burden hours estimate is attributable to an increase in the number of respondents submitting generic drug applications.

Dated: September 16, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–20521 Filed 9–21–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–P–3232]**

### Determination That Prescription NIX (Permethrin) 1% Topical Creme Rinse Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA, Agency, or we) has determined that prescription NIX (permethrin) 1% topical creme rinse was not withdrawn from sale for reasons of safety or effectiveness. However, because NIX (permethrin) 1% topical creme rinse has been approved for nonprescription use, NIX and any generic product referencing prescription NIX would be misbranded under FDA regulations if marketed with the ''Rx only'' symbol. Moreover, FDA will not approve abbreviated new drug applications (ANDAs) referencing prescription NIX (permethrin) 1% topical creme rinse.

**FOR FURTHER INFORMATION CONTACT:** Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 301–796–3977, *Linda.Jong@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

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.

Prescription NIX (permethrin) 1% topical creme rinse (Prescription NIX) is the subject of NDA 019435, held by GlaxoSmithKline, and initially approved on March 31, 1986. Prescription NIX is indicated for the treatment of head lice.

On May 2, 1990, FDA approved a second NDA (NDA 019918) submitted by GlaxoSmithKline, removing its NIX (permethrin) 1% topical creme rinse for the treatment of head lice from the prescription dispensing requirements of section 503(b) of the FD&C Act (21 U.S.C. 353(b)). When it submitted NDA 019918, GlaxoSmithKline stated that it would no longer market the prescription product. GlaxoSmithKline later informed FDA that it had discontinued marketing of the prescription product on June 14, 1990. NDA 019918 is now held by MedTech Products, which continues to use the trade name NIX for this nonprescription product. The approval of NDA 019918 resulted in what is commonly referred to as a ''full Rx to OTC switch'' for NIX (permethrin) 1% topical creme rinse. In a letter dated April 12, 2002, and an amendment to that letter dated July 31, 2020, GlaxoSmithKline requested withdrawal of approval of NDA 019435 for prescription NIX (permethrin) 1% topical creme rinse. In the **Federal Register** of December 23, 2020 (85 FR 83973), FDA announced that it was withdrawing approval of NDA 019435, effective January 22, 2021.

Lachman Consultants submitted a citizen petition dated July 2, 2019 (Docket No. FDA–2019–P–3232), under 21 CFR 10.30, requesting that the Agency determine whether prescription NIX (permethrin) 1% topical creme rinse (NDA 019435) was withdrawn from sale for reasons of safety or effectiveness.

#### II. FDA Has Determined That Prescription NIX Was Not 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 prescription NIX (permethrin) 1% topical creme rinse (NDA 019435) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that prescription NIX (permethrin) 1% topical creme rinse (NDA 019435) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of prescription NIX (permethrin) 1% topical creme rinse (NDA 019435) 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 prescription NIX (permethrin) 1% topical creme rinse (NDA 019435) 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.

#### III. Under Section 503 of the FD&C Act, NIX and Any Generic Product Referencing Prescription NIX Would Be Misbranded if Marketed as Prescription Drugs

According to section 503(b)(4)(B) of the FD&C Act, a drug not required to be dispensed with a prescription under section 503(b)(1) of the FD&C Act shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the ''Rx only'' symbol. Likewise, per section 503(b)(4)(A) of the

FD&C Act, drugs that must be dispensed with a prescription under section 503(b)(1) of the FD&C Act must bear the ''Rx only'' symbol; if not, they become misbranded. FDA has long interpreted these provisions to mean that section 503(b) of the FD&C Act does not permit the same active ingredient to be simultaneously marketed in both a prescription drug product and a nonprescription drug product unless a meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner.

In this instance, based on studies submitted by the sponsor, FDA determined that the original prescription NIX product no longer met the criteria in section 503(b)(1) of the FD&C Act for prescription use (see 21 CFR 310.200(b)). Therefore, FDA changed NIX's status from prescription to nonprescription. This is commonly referred to as a ''full Rx to OTC switch.'' The permethrin 1% topical creme rinse product (NDA 019918) continued to use the trade name NIX when it switched from prescription to nonprescription. Because FDA concluded that there is no meaningful difference between the currently marketed nonprescription NIX product and its previous prescription version, NIX would be misbranded under section 503(b)(4)(B) of the FD&C Act if it were to bear the symbol ''Rx only.'' Similarly, any generic product referencing prescription NIX (NDA 019435) would also be misbranded under section 503(b)(4)(B) of the FD&C Act, because it would necessarily bear the same labeling as that approved under NDA 019435, including the ''Rx only'' symbol. Moreover, FDA will not approve an ANDA referencing prescription NIX (NDA 019435).

Dated: September 14, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–20520 Filed 9–21–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–1358]**

### How To Obtain a Covered Product Authorization; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''How To Obtain a Covered Product Authorization.'' This guidance describes how eligible product developers can obtain a Covered Product Authorization (CPA) from FDA under the law widely known as the CREATES Act. The CREATES Act provides a pathway for eligible product developers to obtain access to the product samples they need to fulfill testing and other regulatory requirements to support their applications. As described in further detail below, to make use of this pathway, an eligible product developer seeking to develop a product subject to a Risk Evaluation and Mitigation Strategies (REMS) with elements to assure safe use (ETASU) must obtain a CPA from the Agency. This guidance replaces the December 2014 draft guidance for industry ''How To Obtain a Letter From FDA Stating That Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD,'' which has been withdrawn. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by November 21, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by November 21, 2022.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2022–D–1358 for ''How To Obtain a Covered Product Authorization.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available