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.'' FDA 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 for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7973, Fax: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will hear an update on supplemental new drug application 208447/S–025, for ZEJULA (niraparib) capsules, submitted by GlaxoSmithKline, LLC., for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The update includes the final overall survival data from the NOVA trial. Based on the information provided, the committee will consider whether the indication should remain in the U.S. labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before November 7, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 28, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 31, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20524 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–N–1517]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 24, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or

by using the search function. The OMB control number for this information collection is 0910–0669. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Abbreviated New Animal Drug Applications—Section 512(b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1))

OMB Control Number 0910–0669—Extension

Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an ANADA is described in section 512(n)(1) of the FD&C Act. Among other things, an ANADA is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved new animal drug. We allow applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review. Applicants may submit Form FDA 356v with a complete ANADA or a phased review submission to ensure efficient and accurate processing of information. Form FDA 356v is approved under OMB control number 0910–0032. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

The information collection also includes applicant requests to waive the requirement to establish bioequivalence through in vivo studies (biowaiver requests) for soluble powder oral dosage form products or certain Type A medicated articles based upon either of two methods. We use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request. Therefore, the information collection references the guidance document GFI #171 ''Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to Be Soluble in Aqueous Media'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-171-demonstrating-bioequivalence-soluble-powder-oral-dosage-form-products-and-type-medicated*) (May 2021), which discusses statutory bioequivalence requirements as well as qualifications for requesting a waiver from the requirements. The guidance document was developed consistent with the Agency's Good Guidance Practice regulations in 21 CFR 10.115, which provide for comment at any time.

The reporting associated with ANADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(2) of the FD&C Act. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

Description of Respondents: The respondents for this collection of information are veterinary pharmaceutical manufacturers.

In the **Federal Register** of March 18, 2022 (87 FR 15436), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received and considered one comment requesting the posting of new animal drug applications for public access. While FDA posts a summary of the safety and effectiveness data and information submitted in the application, which supports the basis for FDA's approval (*https://www.fda.gov/animal-veterinary/approved-animal-drug-products-green-book/freedom-information-foi-summaries-approved-animal-drugs*), we are prohibited from disclosing commercial confidential information contained in an ANADA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	20	1	20	159	3,180
Phased review with administrative ANADA	356v	6	5	30	31.8	954
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach	N/A	5	1	5	10	50
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach	N/A	2	1	2	5	10
Biowaiver request for Type A medicated article, using same API/solubility approach	N/A	5	1	5	20	100
Total				63		4,299

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our records of generic animal drug applications. We estimate that we will receive 26 ANADA submissions per year over the next 3 years and that 6 of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated five ANADA phased review submissions and the administrative ANADA. Our estimates of the burden of biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles differ based on the type of product and the basis for the request, as shown in table 1. We estimate that an applicant will take between 5 and 20 hours to prepare a biowaiver request.

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