OMB has now approved the information collection and has assigned OMB control number 0910–0623. The approval expires on February 28, 2027. A copy of the supporting statement for this information collection is available on the internet at *https://www.reginfo.gov/public/do/PRAMain.*

Dated: March 21, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06395 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–4636]

Determination That ISUPREL (Isoproterenol Hydrochloride) Injection, 0.2 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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we) has determined that ISUPREL (isoproterenol hydrochloride) injection, 0.2 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Veniqua Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3627, *Veniqua.Stewart@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.

ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, is the subject of NDA 010515, held by Bausch Health US, LLC, and was initially approved on May 25, 1956. ISUPREL injection is indicated to improve hemodynamic status in patients in distributive shock and shock due to reduced cardiac output, and is also indicated for bronchospasm occurring during anesthesia. ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

E. Rust Consulting, LLC submitted a citizen petition dated October 20, 2023 (Docket No. FDA–2023–P–4636), under 21 CFR 10.30, requesting that the Agency determine whether ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, 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 ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, 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 ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, 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. ANDAs that refer to ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, may 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: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06311 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0846]

Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for a voluntary

survey for the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the Department of Homeland Security (DHS), which will inform the FDA Food Safety Modernization Act (FSMA), National Agriculture and Food Defense Strategy (NAFDS) Report to Congress. The proposed survey will be used to determine what food defense activities, if any, State, local, territorial, and/or tribal (SLTT) agencies have completed to date. The information will be compared to the initial baseline data previously collected by State(s).

DATES: Either electronic or written comments on the collection of information must be submitted by May 28, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 28, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–0846 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 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 to 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 this 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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St, North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA''s functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

National Agriculture and Food Defense Strategy Survey

OMB Control Number 0910–0855—Extension

We are seeking OMB approval of the NAFDS under section 108 of FSMA. This is a voluntary survey of SLTT governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory NAFDS

followup Report to Congress. The authority for us to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by SLTT governments as well as private sector partners. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA–NAFDS requires HHS and USDA, in coordination with DHS, to work together with SLTT to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how Federal agencies, in cooperation with SLTT governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (*i.e.,* 2019, 2023, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or SLTT agencies have completed (or are planning on completing) from 2024 to 2028. Planning for the local, territorial, and tribal information collections will commence during this period of renewal. The survey will continue to be repeated approximately every 2 to 4 years, as described in section 108 of FSMA. The NAFDS survey is being administered for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy is employed, such that the government agencies participating in food and agricultural defense are asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction are identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the *FDA.gov* web portal, and results will be analyzed by the interagency working group.

Description of Respondents: Respondents to this collection are SLTT government representatives (survey respondents) who are food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdictions.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SLTT Surveys	500	1	500	0.33 (20 minutes)	165

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

The FDA Office of Partnerships reviewed the questionnaire and provided the estimate of time to complete the survey. The total burden is based on our previous experiences conducting surveys. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06316 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1056]

Clovis Oncology, Inc., AstraZeneca Pharmaceuticals LP, and GlaxoSmithKline LLC; Withdrawal of Approval of the Indications for Advanced Ovarian Cancer for Poly (ADP-Ribose) Polymerase Inhibitors RUBRACA (Rucaparib) Tablets, LYNPARZA (Olaparib) Tablets, and ZEJULA (Niraparib) Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for the treatment of adult patients with advanced ovarian cancer for poly (ADP-ribose) polymerase (PARP) inhibitors under three new drug applications (NDAs) from multiple applicants. The applicants Clovis Oncology, Inc. (Clovis), AstraZeneca Pharmaceuticals LP (AZ), and GlaxoSmithKline, LLC (GSK) have each voluntarily requested that the Agency withdraw approval of the indications for the treatment of adult patients with advanced ovarian cancer for their respective PARP inhibitors and waived their opportunities for hearings. Applicant and indication details are further discussed in **SUPPLEMENTARY INFORMATION**.

DATES: Approval is withdrawn as of March 26, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–