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.

In the **Federal Register** of March 26, 2024 (89 FR 20980), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16616 Filed 7–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0758]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Plant Varieties Intended for Food Use

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 August 28, 2024.

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 0910–0583. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

New Plant Varieties Intended for Food Use

OMB Control Number 0910–0583—Extension

This information collection supports recommendations found in FDA guidance pertaining to new plant varieties intended for food use.

I. Consultation Procedures: Foods Derived From New Plant Varieties; Form FDA 3665

The Agency guidance document entitled ''Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived From New Plant Varieties'' (October 1997), which is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant,* describes our consultation process for the evaluation of information on new plant varieties provided by developers. We believe this consultation process will help ensure that human and animal food safety issues or other regulatory issues (*e.g.,* labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development and will help to ensure that market entry decisions by the industry are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Since 1992, when we issued our ''Statement of Policy: Foods Derived From New Plant Varieties'' (the 1992 policy) (57 FR 22984, May 29, 1992), we have encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with us during the plant development process to discuss possible scientific and

regulatory issues that might arise. In the 1992 policy, we explained that under the FD&C Act developers of new foods (in this document food refers to both human and animal food) have a responsibility to ensure that the foods they offer to consumers are safe and in compliance with all requirements of the FD&C Act. To initiate a New Plant Variety consultation (also known as a Biotechnology Notification File (BNF)), developers are encouraged to electronically submit their scientific information and data following a step-by-step process to complete Form FDA 3665, assemble their notification, and send fully electronic submissions to FDA via the Center for Food Safety and Applied Nutrition Online Submission Module (COSM), which may be accessed at *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm.* Firms that prefer to submit a paper notification in a paper format of their choosing or as electronic files on physical media with a paper signature page, have the option to do so; however, Form FDA 3665 prompts a notifier to input the elements of a BNF in a standard format that we will be able to review efficiently. Form FDA 3665 may be accessed at *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

II. Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Form FDA 3666

Since we issued the 1992 policy on foods derived from new plant varieties, including those varieties that are developed through biotechnology, we have encouraged developers of new plant varieties to consult with us early in the development process to discuss possible scientific and regulatory issues that might arise. The guidance, entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' (June 2006), which is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced,* continues to foster early communication by encouraging developers to submit to us their evaluation of the food safety of their new proteins. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of the new protein.

We believe that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins produced by new plant varieties, including biotechnology-derived food plants, and the procedures for communicating with us about the safety evaluation. To initiate an Early Food Safety Evaluation consultation (also known as a New Protein Consultation (NPC)), developers are encouraged to electronically submit their scientific information and data following a step-by-step process to complete Form FDA 3666, assemble their notification, and send fully electronic submissions to FDA via COSM, which may be accessed at *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm.* Firms that prefer to submit a paper NPC in a paper format of their choosing or as electronic files on physical media with a paper signature page, have the option to do so; however, Form FDA 3666 prompts a notifier to input the elements of an NPC in a standard format that we will be able to review efficiently. Form FDA 3666 may be accessed at *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

In the **Federal Register** of March 12, 2024 (89 FR 17854), we published a 60-day notice soliciting comment on the proposed collection of information. Several comments were received. Most comments indicated that the information collected was necessary and had practical utility which allows FDA to make decisions regarding food safety and protection of the public's health. Some of the comments also indicated that the use of automation such as electronic forms made the process of submitting information much quicker and smoother for the respondent. Two comments received were not related to the PRA and are therefore not discussed. No adjustments to our burden estimates were made in response to the public comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Agency guidance recommendations; information collection	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Consultation Procedures: Foods Derived From New Plant Varieties						
Initial consultation	None	30	2	60	4	240
Final consultation	3,665	12	1	12	150	1,800
Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use						
Six data components	3,666	6	1	6	20	120
Total				78		2,160

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

Based on a review of the information collection since our last request for OMB approval, we have made minor adjustments to update our burden estimate to reflect recent annual response rates (increased initial consultations under the New Plant Variety consultation procedures) and to clarify the total number of responses under the Early Food Safety Evaluation procedures.

Dated: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16617 Filed 7–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3248]

Fosun Pharma USA Inc., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 28, 2024.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 073462 ..	Tolmetin Sodium capsule, Equivalent to (EQ) 400 milligrams (mg) base.	Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540.
ANDA 073588 ..	Tolmetin Sodium tablet, EQ 200 mg base	Do.
ANDA 074002 ..	Tolmetin Sodium tablet, EQ 600 mg base	Do.
ANDA 075631 ..	Ketorolac Tromethamine injectable, 15 mg/milliliters (mL) and 30 mg/mL.	Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015.
ANDA 076427 ..	Milrinone Lactate injectable, EQ 1 mg base/mL	Do.
ANDA 076791 ..	Haloperidol Lactate injectable, EQ 5 mg base/mL	Do.
ANDA 076828 ..	Haloperidol Lactate injectable, EQ 5 mg base/mL	Do.
ANDA 077040 ..	Citalopram Hydrobromide tablet, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base.	Fosun Pharma USA Inc.
ANDA 077947 ..	Fluconazole injectable, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL).	Baxter Healthcare Corp.
ANDA 078197 ..	Granisetron Hydrochloride (HCl) injectable, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL).	Do.
ANDA 079045 ..	Bicalutamide tablet, 50 mg	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 085787 ..	Trifluoperazine HCl concentrate, EQ 10 mg base/mL	Fosun Pharma USA Inc.
ANDA 086808 ..	Cyproheptadine HCl tablet, 4 mg	Do.
ANDA 087774 ..	Phenylbutazone capsule, 100 mg	Do.
ANDA 088602 ..	Pseudoephedrine HCl; Triprolidine HCl tablet, 60 mg; 2.5.mg	Do.
ANDA 090367 ..	Levofloxacin tablet, 250 mg, 500 mg, 750 mg	Celltrion USA, Inc., U.S. Agent for Celltrion, Inc., One Evertrust Plaza, Suite 1207, Jersey City, NJ 07302.
ANDA 091049 ..	Ceftriaxone Sodium injectable, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, EQ 2 g base/vial.	EAS Consulting Group, LLC, U.S. Agent for Astral SteriTech Pvt. Ltd., 1700 Diagonal Rd., Suite 750, Alexandria, VA 22314.
ANDA 091436 ..	Levofloxacin injectable, EQ 500 mg/20 mL (EQ 25 mg/mL)	Baxter Healthcare Corp.
ANDA 207032 ..	Melphalan HCl injectable, EQ 50 mg base/vial	USWM, LLC, 4441 Springdale Rd., Louisville, KY 40241.
ANDA 207101 ..	Sumatriptan Succinate injectable, EQ 6 mg base/0.5 mL (EQ 12 mg base/mL).	Baxter Healthcare Corp.
ANDA 211959 ..	Clobazam tablet, 10 mg and 20 mg	Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.
ANDA 212053 ..	Chlorzoxazone tablet, 375 mg and 750 mg	AptaPharma Inc., 1533 Union Ave., Pennsauken, NJ 08110.
ANDA 215065 ..	Methocarbamol solution, 1 g/10 mL (100 mg/mL)	Baxter Healthcare Corp.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of August 28, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on August 28, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16627 Filed 7–26–24; 8:45 am]

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