specifically called for in Section 1313(a)(1) of the Act which requires a State Based Exchange (including an Exchange using the Federal Platform) to keep an accurate accounting of all activities, receipts, and expenditures, and to submit a report annually to the Secretary concerning such accounting. CMS will use the information collected from States to assist in determining if a State is maintaining a compliant operational Exchange. *Form Number:* CMS–10507 (OMB control number: 0938–1244); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal governments; *Number of Respondents:* 21; *Total Annual Responses:* 21; *Total Annual Hours:* 4,281. (For policy questions regarding this collection contact Shilpa Gogna at 301–492–4257.)

Dated: July 14, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–15404 Filed 7–19–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0921]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 19, 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 0910–0816. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; 21 CFR Part 112

OMB Control Number 0910–0816—Extension

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, we have established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. The standards are codified in part 112 (21 CFR part 112) and set forth procedures and processes that include information collection activities such as establishing monitoring and sampling plans, documenting data and training, and ensuring disclosure that produce for human consumption meets these requirements. The regulations also provide for certain exemptions and variances to qualified respondents. The information collection continues to implement provisions of the FDA Food Safety Modernization Act, while certain requirements for covered produce other than sprouts associated with pre-harvest agricultural water testing are being amended through rulemaking (RIN 0910–AI49). We use the information to verify that the standards established by the regulations are followed such that produce entering the marketplace is reasonably unlikely to be associated with foodborne illness.

In addition to the referenced regulations, we have developed two draft guidance documents: ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' and ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations;'' both are available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm.* The former was developed to help covered farms comply with the requirements of the Produce Safety regulation. This draft guidance, when finalized, will not create any additional burden not already considered as part of the Produce Safety regulation.

The latter (the Sprouts draft guidance) was developed to assist sprout operations also subject to the Produce Safety regulation. Sprouts represent a special food safety concern because the conditions under which they are produced (time, temperature, water activity, pH, and available nutrients) are ideal for the growth of pathogens, if present. The Sprouts draft guidance, when finalized, will assist sprout operations subject to the regulations in part 112 in complying with the sprout-specific requirements in subpart M.

Description of Respondents: Respondents to this information collection include farms that grow, harvest, pack, or hold produce for human consumption, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of December 3, 2021 (86 FR 68673), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received and appears to pertain to rulemaking that has already concluded, rather than to this renewal. Significantly, this comment did not suggest that we revise the currently approved estimate. To the extent that the comment relates to ongoing rulemaking, we have posted the comment to the docket at FDA–2021–N–0471 and will ensure it is considered and addressed appropriately.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping	Total hours
Exemptions under § 112.7	3,285	1	3,285	0.5 (30 minutes)	1,643
Training under § 112.30	24,420	1	24,420	7.25	177,045
Testing requirements for agricultural water under §§ 112.44 and 112.45.	48,361	2.990	144,599	0.825 (~50 minutes)	119,294
Records related to agricultural water	160,605	2.242	360,076	2.160	777,765
Testing requirements for sprouts under §§ 112.144, 112.145, and 112.147.	126	245.660	30,953.16	0.825 (~50 minutes)	25,536
Records related to sprouts	126	62.061	7,819.686	1.412 (~85 minutes)	11,041
"Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations".	126	233	29,358	1	29,358
Documentation supporting compliance with § 112.2	4,568	1	4,568	0.079 (~ 5 minutes)	361
Total	241,617		605,079		1,142,043

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers rounded to nearest 1/1,000.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total disclosures	Average burden per disclosure	Total hours
Disclosure under §§ 112.2, 112.6, 112.31, 112.33, and 112.142.	77,165	3.459	266,914	1.422 (~85 minutes)	379,551

[1] There are no capital costs or operating or 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 no adjustments to our burden estimate. As respondents to the collection continue to implement the regulatory requirements and compliance schedules continue to be realized, we retain our current burden estimates. At the same time, and as communicated on our website at *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water,* we expect the burden associated with the testing of certain agricultural water for covered produce other than sprouts to be minimal for the period of time that FDA intends to exercise enforcement discretion with regard to those requirements.

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15425 Filed 7–19–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1526]

Fluorinated Polyethylene Containers for Food Contact Use; Request for Information

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

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is opening a docket to obtain data and information on the use of fluorinated polyethylene for food contact applications. Specifically, FDA is seeking scientific data and information on current food contact uses of fluorinated polyethylene, consumer dietary exposure that may result from those uses, and safety of certain per- and polyfluoroalkyl substances that may migrate from fluorinated polyethylene food containers. The purpose of this request is to ensure that we have current information to support our review of the use of fluorinated polyethylene containers used in food contact applications to help ensure that this use continues to be safe. FDA may use information submitted in response to this notice to update dietary exposure estimates and safety assessments for the authorized food contact use of fluorinated polyethylene.

DATES: Either electronic or written comments and scientific data and information must be submitted by October 18, 2022.

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 October 18, 2022. 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