Closed Committee Deliberations: On March 19, 2019, from 5:45 p.m. to 6 p.m., and March 20, 2019, from 11:30 a.m. to 12 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 Donna Mendrick 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: February 25, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03562 Filed 2–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3631]

Agency Information Collection Activities; Proposed Collection; Comment Request; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

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 information collection associated with the standards for the growing, harvesting, packing, and holding of produce for human consumption.

DATES: Submit either electronic or written comments on the collection of information by April 29, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 29, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 29, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2018–D–3631 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' 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.

- 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.gpo.gov/fdsys/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.

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: Under the PRA (44 U.S.C. 3501–3520), 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.

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

OMB Control Number 0910–0816—Revision

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. We use the information to verify that the standards established by the regulation are followed such that produce entering the marketplace is reasonably assured to be safe.

In addition to the referenced regulations, we have developed a draft guidance entitled ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations'' (''Sprouts draft guidance'') available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm.* 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 draft guidance, when finalized, will assist sprout operations subject to the regulations in part 112 to comply 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).

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity in 21 CFR Part 112	Number of recordkeepers	Number of records per recordkeeper [1]	Total annual records	Average burden per recordkeeping (in hours) [2]	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.	256	245.660	62,889	0.403 (~24 minutes)	25,344
Records related to sprouts	1,023	62.061	63,488	0.174 (~11 minutes)	11,047
Following Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.	1,023	1	1,023	1	1,023
Documentation supporting compliance with § 112.2.	4,568	1	4,568	0.079	361
Total	243,541		664,348		1,113,522

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers rounded to nearest 1/1000.

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

21 CFR Part 112	Number of respondents	Number of disclosures per respondent	Total disclosures	Average burden per disclosure (in hours)	Total hours
Disclosure under §§ 112.2, 112.6, 112.31, 112.33, and 112.142	77,165	3.459	266,914	1.422	379,551

[1] There are no capital costs or operating or maintenance costs associated with annual disclosure.

Section 112.7 (21 CFR 112.7) requires farms eligible for the qualified exemption in accordance with § 112.5 (21 CFR 112.5) to maintain the records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption, including a written record reflecting that the owner, operator, or agent in charge of the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption. We estimate that 3,285 farms are eligible for the qualified exemption and that each farm will spend an average of 0.5 hours per year to maintain one record. Therefore, 3,285 recordkeepers × 0.5 average hours per recordkeeping = 1,642.5 hours (rounded to 1,643) to meet the recordkeeping requirements of § 112.7.

Section 112.30 (21 CFR 112.30) requires the maintenance of records of required training of personnel, including the date of training, topics covered, and persons trained. We estimate that 24,420 farms will maintain one record of required training and spend an average of 7.25 hours per year on recordkeeping. Therefore, 24,420 recordkeepers × 7.25 average hours per recordkeeping = 177,045 hours to meet the recordkeeping requirements of § 112.30.

Section 112.46 (21 CFR 112.46) requires testing agricultural water subject to the requirements of §§ 112.44 and 112.45 (21 CFR 112.44 and 112.45). We estimate that 48,361 farms that will conduct these tests. Thus, it is estimated that about three (2.990) records for each farm will spend an average of 0.825 hours per record on testing water. Therefore, 48,361 farms × 2.990 records × 0.825 average hours per recordkeeping = 119,294.175 hours (rounded to 119,294) to meet the recordkeeping requirements of §§ 112.44 and 112.45.

For records related to agricultural water, FDA estimates that there are 160,605 recordkeepers each maintaining just over 2 records (2.242), with each recordkeeping taking just over 2 hours (2.160). Therefore, 160,605 recordkeepers × 2.242 records × 2.160 hours = 777,765.046 hours (rounded to 777,765) for the recordkeeping burden related to agricultural water.

Sections 112.144, 112.145, and 112.147 (21 CFR 112.144, 112.145, and 112. 147) require testing for sprouts. We estimate that 256 recordkeepers will conduct these tests. Thus, it is estimated that about 245 (245.660) records for each recordkeeper will spend an average of 0.403 hour per record on testing sprouts. Therefore, 256 recordkeepers × 245.660 records × 0.403 average hours per recordkeeping = 25,344.251 hours (rounded to 25,344) to meet the recordkeeping requirements of §§ 112.144, 112.145, and 112.147.

We estimate that there are 1,023 recordkeepers for other records related to sprouts. Thus, it is estimated that about 62 (62.061) records for each recordkeepers will spend an average of 0.174 hour per record. Therefore, 1,023 recordkeepers × 62.061 records × 0.174 average hour per recordkeeping = 11,046.982 (rounded to 11,047) hours for the burden to maintain records related to sprouts.

We estimate 1,023 recordkeepers will utilize the recommendations in the Sprouts draft guidance, once finalized, to maintain additional records related to sprouts. We estimate each recordkeeping will take about an hour for a recordkeeping burden of 1,023 hours.

Section 112.2 relates to documentation supporting compliance. We estimate that there are 4,568 recordkeepers each maintaining a record of compliance. We estimate that each recordkeeper will spend 0.079 hour maintaining their record. Therefore, 4,568 recordkeepers × 0.079 hour = 360.872 (rounded to 361) hours for the burden to maintain documentation supporting compliance.

Sections 112.2, 112.6, 112.31, 112.33, and 112.142 (21 CFR 112.2, 112.6, 112.31, 112.33, and 112.142) require third-party disclosures. We estimate that 77,165 respondents are making these disclosures. Thus, it is estimated that each respondent has around three (3.459) disclosures and will spend an average of 1.422 hours per disclosure. Therefore, 77,165 respondents × 3.459 disclosures × 1.422 average hours per disclosure = 379,551.331 hours (rounded to 379,551) for the third-party disclosure burden to meet the requirements of §§ 112.2, 112.6, 112.31, 112.33, and 112.142.

The burden estimate reflects adjustments resulting in an overall decrease of 19,847 hours. We have removed one-time burden that has been realized since establishing the regulations; however, we have added burden we attribute to our estimate of recordkeepers following the recommendations in the Sprouts draft guidance.

Dated: February 25, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03507 Filed 2–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0407]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 29, 2019.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0407–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any