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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved information collection request; *Title of Information Collection:* Reassignment of Medicare Benefits; *Use:* The reassignment application is submitted at the time the provider/supplier first reassigns of his/her Medicare benefits to a group practice, as well as any subsequent reassignments, changes to current reassignment information or terminations of established reassignments as requested by the provider/supplier or group. The application is used by the Medicare Administrative Contractor (MAC) to collect data to assure the applicant has the necessary information that allows the MAC to correctly establish, change, or terminate the reassignment.

The collection and verification of reassignment information defends and protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Fund against fraud. It gathers information that allow Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. The data (*e.g.,* Social Security Numbers, Employer Identification Numbers) collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare through the reassignment. This is sole instrument implemented for this purpose. *Form Number:* CMS–855R (OMB control number: 0938–1179); *Frequency:* Occasionally; *Affected Public:* Private Sector; Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 357,628; *Number of Responses:* 357,628; *Total Annual Hours:* 89,407. For policy questions regarding this collection, contact Kimberly McPhillips at 410–786–5374.

Dated: June 5, 2019.

William N. Parham, III,

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

[FR Doc. 2019–12118 Filed 6–7–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Delegation of Authority

Notice is hereby given that I have delegated to the Administrator of the Administration for Community Living the following authorities vested in the Secretary:

- The authority to oversee and administer the implementation of the Recognize, Assist, Include, Support, and Engage Family Caregivers Act of 2017 (Pub. L. 115–119), commonly referred to as the ''RAISE Family Caregivers Act''. This authority may be redelegated, but only to an officer or inferior officer as those terms are used in Art. II, § 2, cl. 2 of the U.S. Constitution.

This delegation excludes the authority to issue regulations and appoint non-federal council members, and shall be exercised in accordance with the Department's applicable policies, procedures, and guidance.

Dated: June 3, 2019.

Alex M. Azar II,

Secretary.

[FR Doc. 2019–12140 Filed 6–7–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Delegation of Authority

Notice is hereby given that I have delegated to the Administrator of the Administration for Community Living the following authorities vested in the Secretary:

- The authority to oversee and administer the implementation of the Supporting Grandparents Raising Grandchildren Act (Pub. L. 115–196). This authority may be redelegated, but only to an officer or inferior officer as those terms are used in Art. II, § 2, cl. 2 of the U.S. Constitution.

This delegation excludes the authority to issue regulations and appoint non-federal council members, and shall be exercised in accordance with the Department's applicable policies, procedures, and guidance. This delegation is effective upon date of signature.

Dated: June 3, 2019.

Alex M. Azar II,

Secretary.

[FR Doc. 2019–12141 Filed 6–7–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3631]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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: Fax written comments on the collection of information by July 10, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0816. 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.

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 unlikely to be associated with foodborne illness.

In addition to the referenced regulations, we 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.

In the **Federal Register** of February 28, 2019 (84 FR 6793), we published a 60-day notice requesting public comment on the proposed collection of information. A number of comments were received; however, only those responsive to the information collection topics solicited are discussed here.

(Comment 1) One comment suggested that some entities such as tree nut hullers and shellers may be overly burdened by the definition of a secondary activities farm, which may cause it to be covered by regulations promulgated under the Preventive Controls rule as well as the Produce Safety rule. The comment argues that an entity of this sort should be covered only by the Produce Safety regulation.

(Response) In the **Federal Register** of January 5, 2018 (83 FR 598), we announced the availability of the guidance for industry ''Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs'' in which we indicated our intent to exercise enforcement discretion for the Preventive Controls for Human Food requirements for facilities that would be secondary activities farms except for ownership of the facility.

Our intent is to exercise enforcement discretion for any operation not located on a primary production farm that is dedicated to harvesting, packing, and/or holding raw agricultural commodities while we pursue future rulemaking/solutions to relevant issues. The guidance provides examples of the types of facilities likely to fit within this category as facilities engaged in nut hulling and shelling operations.

(Comment 2) One comment suggested that there should be documentation for the source of all products used for processing produce as well as for daily testing of the water used for produce.

(Response) We assume that the phrase ''products used for processing produce'' refers to herbicides, pesticides, or fertilizers used when growing produce. Under various regulations of FDA and the Environmental Protection Agency, these substances are regulated for proper usage to not endanger human health.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity in 21 CFR part 112	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping [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.	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	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 part 112	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	379,551

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

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 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.

Although compliance dates for the agricultural water provisions (subpart E) for covered produce other than sprouts are delayed to January 26, 2024, for very small businesses, January 26, 2023, for small businesses, and January 26, 2022, for all other businesses, we have estimated the burden. 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, we estimate 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 126 recordkeepers will maintain records for these tests. Thus, it is estimated that for about 246 (245.660) records each recordkeeper will spend an average of 0.825 hour per record on testing sprouts. Therefore, 126 recordkeepers × 245.660 records × 0.825 average hours per recordkeeping = 25,536.357 hours (rounded to 25,536) to meet the recordkeeping requirements of §§ 112.144, 112.145, and 112.147.

We estimate that there are 126 recordkeepers for other records related to sprouts. Thus, it is estimated that for about 62 (62.061) records each recordkeeper will spend an average of 1.412 hours per record. Therefore, 126 recordkeepers × 62.061 records × 1.412 average hours per recordkeeping = 11,041.397 (rounded to 11,041) hours for the burden to maintain records related to sprouts.

We estimate 126 recordkeepers will utilize the recommendations in the draft guidance document 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,'' once finalized, to maintain additional records related to sprouts. We estimate each recordkeeper will keep 233 records and recordkeeping will take about an hour per record for a recordkeeping burden of 29,358 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 increase of 8,515 hours. Although we removed the one-time burden that has been realized since establishing the regulations, we have added burden attributed to recommendations found in the Sprouts draft guidance.

Dated: June 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12108 Filed 6–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4735]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

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