UNITED STATES FOOD & DRUG ADMINISTRATION

Standards for the Growing, Harvesting, Packaging, and
Holding of Produce for Human Consumption

OMB Control No. 0910-0816

SUPPORTING STATEMENT – **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency regulations and associated guidance. To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) has established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. Implementing regulations are found in 21 CFR part 112, and establish procedures, processes, and practices intended to minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce, and to provide reasonable assurances that the produce is not adulterated because of such hazards. The requirements do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity (RAC). In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of 21 CFR part 112.

The information collection also includes recommendations found in the following guidance documents, available at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm:

- "*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*"

- "*Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations*"

While we anticipate finalizing both of the guidance documents, we are currently continuing to review and consider public comment consistent with our Good Guidance Practice Regulations at 21 CFR part 10.115, and we continue to realize certain compliance dates associated with FSMA. The first guidance document was developed to help covered farms comply with certain requirements. It provides a broad range of recommendations on how to meet the requirements for most subparts of the Produce Safety regulation, and also outlines how to determine whether produce or farms may be eligible for exemptions. The latter guidance (the *Sprouts 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. Similarly, the Sprouts draft guidance is intended to assist sprout producers subject to the regulations in part 112 in complying with the sprout-specific requirements in subpart M of the regulations.

Accordingly, we request extension of OMB approval for the information collection provisions found in 21 CFR part 112 (*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*), and included in the associated guidance documents, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Part 112 (21 CFR part 112) establishes procedures, processes, and practices including setting forth monitoring and sampling plans, documenting data and training, and ensuring disclosure that produce for human consumption meets these requirements. Part 112 also provides for certain exemptions and variances to qualified respondents. We use the information collected to verify that the standards are followed such that produce entering the marketplace is reasonably unlikely to be associated with foodborne illness.

Description of Respondents: Respondents to this collection of information 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).

3. Use of Improved Information Technology and Burden Reduction

We believe this information collection imposes minimum burden. While it does not so require, we believe 100% of respondents affected by this collection will rely on information technology to store, retrieve, and otherwise comply with data collection requirements. Additionally, FDA is currently exercising enforcement discretion, as communicated on our website at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water, with regard to the testing of agricultural water and pending rulemaking; and we therefore expect any attendant burden to be minimal.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection does not impose undue burden on small entities. At the same time, the regulations in 21 CFR part 112 provide for exemptions for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, and provide for modified requirements for farms meeting specific criteria.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment
in the Federal Register of December 3, 2021 (86 FR 68673). One comment was received and appears to pertain to rulemaking that has already concluded, rather than to this extension request. Significantly, the 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.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 482 (Notice of Inspection) is name. We have determined that although PII is collected, the information collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property

rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden[1]

Activity; 21 CFR section	No. of Recordkeepers	No. of Records per Recordkeeper[2]	Total Annual Records	Avg. Burden per Record	Total Hours
Exemptions under § 112.7	3,285	1	3,285	0.5 (30 mins.)	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 mins.)	119,294
Records related to agricultural water under § 112.50	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 mins.)	25,536
Records related to sprouts under § 112.150	126	62.061	7,819.686	1.412 (85 mins.)	11,041
Recommended measures found in agency GFI (*Sprouts Guidance*) pertaining to sprout operations	126	233	29,358	1	29,358
Documentation supporting compliance with § 112.2	4,568	1	4,568	0.079 (5 mins.)	361
TOTAL			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]

Activity; 21 CFR section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. 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 mins.)	379,551

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

As respondents to the collection continue to implement the regulatory requirements and compliance schedules continue to be realized, we retain our current burden estimates.

12b. Annualized Cost Burden Estimate

Table 3.--Estimated Annual Cost Burden

Recording Activity	Very Small	Small	Large	Total
Qualified exempt farms labeling and documentation	$5,239	$469	$0	$5,708
Agricultural water; § 112.50	$4,510	$829	$1,043	$6,382
Biological soil amendments of animal origin; § 112.60	$184	$32	$40	$256
Equipment, tools, buildings, and sanitation; § 112.140	$4,829	$2,620	$5,492	$12,941
Sprouting operations; § 112.150	$108	$109	$484	$701
Training; § 112.30	$1,069	$186	$227	$1,482
Documentation relating to commercial processing	$13	$3	$3	$19
TOTAL	$15,952	$4,248	$7,289	$27,489

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no other costs associated with the information collection.

14. Annualized Cost to the Federal Government

The information collection is administered through existing resource allocations. Therefore, we estimate no annualized cost to the Federal government.

15. Explanation for Program Changes or Adjustments

Based on our evaluation of the information collection since OMB's last review and approval, we have made no adjustment to the currently approved burden estimate. We have removed costs previously reflected in our last submission under Question 12.a, as we account for annualized costs under Question 12.b.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of data resulting from this information collection is planned or anticipated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice, once these draft guidance documents are finalized, FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with the finalized guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on each finalized guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.