## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–4250]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment, Maintenance, and Availability of Records; Additional Traceability Records for Certain Foods

**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 July 13, 2026.

**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 0910–0560. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Michael Ellison, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–2093, *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.

### Establishment, Maintenance, and Availability of Records; Additional Traceability Records for Certain Foods—21 CFR Part 1, Subparts J and S

*OMB Control Number 0910–0560—Reinstatement*

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. These requirements are codified in the agency's general enforcement regulations at 21 CFR part 1, subpart J. The FDA Food Safety Modernization Act (FSMA) signed in 2011, required FDA to establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods the Agency designates as high-risk to facilitate the rapid and effective traceability of such foods. These requirements are codified in the agency's general enforcement regulations at 21 CFR part 1, subpart S. Part 1, subpart J (21 CFR 1.326 through 1.368) sets forth the requirements for recordkeeping and records access. Part 1, subpart S (21 CFR 1.1300 through 1.1465) provides additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods FDA has designated as high-risk in accordance with factors specified by Congress; we have listed these foods on the Food Traceability List (FTL) on our website at *https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list.* The requirement to establish and maintain records improves our ability to respond to, and further contain, threats of serious adverse health consequences or death from contaminated food.

Part 1, Subpart J

Information maintained under these regulations helps us identify and quickly locate contaminated or potentially contaminated food and inform the appropriate individuals and food facilities of specific terrorist threats. Our regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters; an adequate description of the food, including the quantity and packaging; and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all the required information and are retained for the required time period.

The information collection provisions of § 1.361 are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations at 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361.

Part 1, Subpart S

Part 1, subpart S, in accordance with FSMA, establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods that the Agency has designated as high-risk foods (*i.e.,* placed on the ''Food Traceability List'' (FTL)) in accordance with section 204(d)(2) of FSMA. Persons are required to maintain records containing information on critical tracking events in the supply chain for FTL foods. Part 1, subpart S will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. These additional recordkeeping requirements strengthen public health protections by documenting the movement of foods on the FTL throughout the supply chain, enabling FDA to more rapidly and effectively identify the source of contaminated foods and aid in the removal of contaminated products from the market. Records required under this subpart must be maintained for 2 years from the date they were created or obtained. For more information about requirements for additional traceability records for certain foods visit our website at *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods,* which also includes a guide that provides key data elements for recordkeeping (*https://www.fda.gov/media/163132/download?attachment*).

The information and records required under part 1, subpart S vary depending on the type of supply chain activities performed with respect to an FTL food. For harvesting and cooling of foods on the FTL, records must include

information about the location for the immediate subsequent recipient, commodity, quantity, location of farm and harvest area or cooling area, date of harvest or cooling, and the reference document type and reference document number (§ 1.1325). For the initial packing of a raw agricultural commodity on the FTL, including sprouts, for each traceability lot you initially pack, records must include and link the traceability lot to information about the commodity, date harvested and received, quantity, location of farm and harvest and/or cooling area, name and phone number of harvester, and the reference document type and reference document number (§ 1.1330). For the first land-based receiver of food on the FTL, for each traceability lot obtained from a fishing vessel, records must include and link the traceability lot to the traceability lot code assigned, product description, quantity, harvest date range and locations, location of land-based receiver, date the food landed, and the reference document type and reference document number (§ 1.1335). For each traceability lot of a food on the FTL that you ship or receive, records must include and link the traceability lot to the traceability lot code, product description, quantity, location description of either the immediate subsequent recipient or the immediate previous source, location description of either from which you shipped or for where the food was received, date the food was shipped or received, location description for the traceability lot code source, and the reference document type and reference document number (§§ 1.1340 and 1.1345). For each traceability lot of food that is on the FTL that is transformed, records must include and link the traceability lot to the traceability lot code, product description, quantity, date transformed, and the reference document type and reference document number (§ 1.1350). Part 1, subpart S also requires that persons who manufacture, process, pack, or hold foods listed on the FTL to maintain records demonstrating the creation and establishment of a traceability plan (§ 1.1315).

A respondent may submit a citizen petition to FDA to request modified requirements or exemptions from the requirements of subpart S (§ 1.1370). In addition to the requirements of a citizen petition (21 CFR 10.30), a respondent must: (a) specify the food or type of entity to which the modified requirements or exemption would apply; (b) specify the proposed modifications to the requirements; and (c) provide information demonstrating that the proposed modification or exemption of the requirements are not necessary to protect the public health.

A respondent may submit to FDA a written request or a citizen petition to waive one or more requirements (§§ 1.1415 and 1.1425). In addition to the requirements for submitting a citizen petition (§ 10.30), a respondent must: (a) specify the type of entity to which the waiver would apply; (b) provide information demonstrating why the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements; and (c) why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and (d) provide information demonstrating that the waiver would not otherwise be contrary to the public interest.

The information collection provision of § 1.1455(c)(3)(ii) is exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations at 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records for which there is a requirement to provide the records in an electronic sortable spreadsheet under § 1.1455(c)(3)(ii). Accordingly, we have not included an estimate of burden hours associated with § 1.1455(c)(3)(ii).

*Description of Respondents:* Respondents to this collection of information are persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States who are required to establish, maintain, and provide records, including persons that engage in both interstate and intrastate commerce.

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the **Federal Register** of December 9, 2025 (90 FR 57074). One stakeholder provided multiple comments. Although the commenter generally supported collections of information to support public safety, there were several comments that questioned the extent of the number of food facilities creating and maintaining records and whether the necessity to maintain such records had practical utility. Another comment offered concern with the cost to comply for smaller businesses.

As explained earlier in this document, this collection of information supports regulations in 21 CFR part 1, subparts J and S. FDA codified the subpart J regulations to support the Bioterrorism Act (Pub. L. 107–188) and, subsequently, implemented additional recordkeeping requirements in subpart S for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA (Pub. L. 111–353). In other words, FDA implemented these regulations and required this collection of information as directed by Congress.

These recordkeeping requirements are appropriate and necessary to protect the public health. These traceability recordkeeping requirements help FDA rapidly and effectively identify recipients of certain foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated under the FD&C Act. The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination. If all facilities did not create and maintain records, there would be instances that FDA would not be able to quickly and effectively identify recipients of contaminated food. That could result in additional serious adverse health consequences or death. It could also adversely impact the food industry by not being able to identify specific lot numbers or batches of product in question, resulting in overly broad recall requests that affect entire segments of the industry. The recordkeeping requirements of these regulations are mandated by section 414 of the FD&C Act, and there is no statutory exception for small businesses. However, in the promulgating regulations to implement the statutory

requirements, FDA provides relief for small businesses in the form of exemptions and partial exemptions set forth in §§ 1.327 and 1.1305. FDA also help small businesses comply with our requirements through our Regional Small Business Representatives and via the agency's website at *https://www.fda.gov/industry/small-business-assistance.* The regulations also allow for requests to modify or exempt requirements and for waivers.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity; 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Requests for modified requirements and exemptions; 1.1370 | 5 | 1 | 5 | 10 | 50 |
| Requests for waivers; 1.1415 through 1.1425 | 15 | 1 | 15 | 10 | 150 |
| Total | | | 20 | | 200 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity; 21 CFR section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Records maintenance; 1.337, 1.345, and 1.352 | 379,493 | 1 | 379,493 | 7 | 2,656,451 |
| Create and establish traceability plan; 1.1315 | 212,368 | 1 | 212,368 | 8 | 1,698,944 |
| Records for harvesting or cooling; 1.1325 | 9,570 | 575 | 5,502,750 | 0.07 (4 minutes) | 385,193 |
| Records for initial packer; 1.1330 | 4,313 | 865 | 3,730,745 | 0.07 (4 minutes) | 261,152 |
| Records for first land-based receiver;1.1335 | 367 | 1,471 | 539,857 | 0.03 (2 minutes) | 16,196 |
| Records for shipper and receiver; 1.1340 and 1.1345 | 502,000 | 5,900 | 2,961,800,000 | 0.006 (20 seconds) | 17,770,800 |
| Transformer; 1.1350 | 8,574 | 1,101 | 9,439,974 | 0.03 (2 minutes) | 283,199 |
| Total | | | 2,981,605,187 | | 23,071,935 |

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

The revised estimated annual burden reflects updates to the consideration of burden. We believe that the burden for part 1, subpart J was inadvertently omitted from the previous approval, so we are adding it here. However, we believe some of the considerations for burden should have been incorporated with PRA activities instead of being considered independently. Lastly, considerations of burden for §§ 1.1465(a) and 1.1455(c)(3)(ii) do not apply to the PRA so we have removed this burden. Section 1.1465(a) is a general solicitation for comment, which is not considered ''information'' under the PRA regulations (5 CFR 1320.3(h)(4)). Activities under § 1.1455(c)(3)(ii) applies to an investigation, audit, or action after a case file is opened for a specific party, which is exempt from OMB review as discussed earlier in this document (5 CFR 1320.4(a)(2)).

Our estimated burden for the information collection reflects an overall increase of 4,227,299 hours but a corresponding decrease of 4,973,420 records. We attribute the increase in hours to the return of burden for part 1, subpart J along with adjustments to the average burden per recordkeeping. We attribute the decrease in records due to the reconsideration of activities such as learning new requirements and training staff and incorporating the time for these activities as part of the actual information collection.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–4492]**

### Drug Repurposing for Unmet Medical Needs; Request for Information; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for information; establishment of a public docket.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the notice entitled ''Drug Repurposing for Unmet Medical Needs; Request for Information'' that appeared in the **Federal Register** of May 12, 2026 (91 FR 25897). In the notice, FDA requested comments to solicit input on FDA's efforts with respect to drug repurposing to address unmet medical needs. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period for the notice published May 12, 2026 (91 FR 25897). Submit either electronic or written comments, data, or information by July 13, 2026.

**ADDRESSES:** You may submit comments, data, and information 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 July 13, 2026. 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,