regardless of their employment status in 2020–2021.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Home-based Provider Interview, Waves 1 and 2	3,375	1.5	.33	1,671
Center-based Provider Interview, Waves 1 and 2	5,850	1.5	.33	2,896
Center-based Classroom Staff (Workforce) Interview, Waves 1 and 2	3,533	1.5	.33	1,749

Estimated Total Annual Burden Hours: 6,316.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Child Care and Development Block Grant Act (42 U.S.C. 9858 et seq.).

John M. Sweet Jr,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–16550 Filed 7–29–20; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0016]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

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 August 31, 2020.

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: 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. Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352.

OMB Control Number 0910–0560—Extension

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. Sections 1.326 through 1.363 of our regulations (21 CFR 1.326 through 1.363) set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves our ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

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: (1) The name and full contact information of sources, recipients, and transporters; (2) an adequate description of the food, including the quantity and packaging; and (3) 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.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded our access to records. Specifically, FSMA expanded our access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that we reasonably believe is likely to be affected in a similar manner. In addition, we can access records if we believe that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. To gain access to these records, our officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner.

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 in table 1.

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 and maintain records, including persons that engage in both interstate and intrastate commerce.

In the **Federal Register** of April 7, 2020 (85 FR 19489), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	6.61	2,508,449
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.5	85,388
Total					2,593,837

[1] There are no capital costs or operating and 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 adjustments to our burden estimate to account for advances in information and communication technology that have occurred in the last decade. Because the transition from paper-based to electronic records systems is widespread, we estimate that the average burden per recordkeeping has decreased by 50 percent. With regards to records maintenance, we estimate that approximately 379,493 facilities each spend half the amount of time from the 13.228 hours previously reported to 6.61 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 2,508,449 hours annually. In addition, we estimate that new firms entering the affected businesses incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, we estimate the number of new firms entering the affected businesses is 5 percent of 379,493, or 18,975 firms. Thus, we estimate that approximately 18,975 facilities each spend, on average, 4.5 hours learning about the recordkeeping and records access requirements, for a total of 85,388 hours annually. This estimate reflects a reduction from 4.79 to 4.5 average hours per facility to account for the increase in facilities using internet, which increased from 71 to 99 percent. We estimate that approximately the same number of firms (18,975) exit the group of affected businesses in any given year, resulting in no growth in the number of total firms reported on line 1 of table 1.

Dated: July 24, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16546 Filed 7–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0829]

Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products.'' The guidance describes the circumstances under which FDA generally does not intend to take action regarding required stability studies for unit-dose repackaged solid oral dosage form drug products and appropriate expiration dates under those circumstances. This guidance finalizes the revised draft guidance for industry issued in August 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on July 30, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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