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]

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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

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–2017–D–0829 for ''Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products.'' Received comments 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.govinfo.gov/content/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Bill Harvey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 4214, Silver Spring, MD 20993–0002, 240–402–4180.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products.'' The last few decades have seen an increasing demand in various health care settings for solid oral dosage form drug products repackaged into unit-dose containers, which hold a quantity of drug for administration as a single dose. The increase in unit-dose repackaging has led to questions regarding stability studies and appropriate expiration dates for these repackaged products. This guidance describes the circumstances under which FDA generally does not intend to take action regarding required stability studies for these repackaged products and appropriate expiration dates under those circumstances.

This guidance finalizes the revised draft guidance of the same name issued in August 2017 (82 FR 37229). FDA received a few comments on the revised draft guidance and has modified this guidance by: (1) Describing why liquid dosage forms are excluded, (2) indicating approaches that may be used when conducting stability studies, and (3) making editorial changes to update references and improve clarity. Liquid dosage forms are substantially more susceptible to degradation than solid dosage forms. Because of the inherent stability risks, FDA does not intend to exercise enforcement discretion regarding the stability and expiration dating requirements in 21 CFR 211.137 and 211.166 for repackaging liquid dosage forms.

In conjunction with the publication of this guidance, FDA withdraws Compliance Policy Guide 480.200, ''Expiration Dating of Unit-Dose Repackaged Drugs,'' issued February 1, 1984, revised March 1995.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved collections of information that are subject to review by the OMB under the PRA. The collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: July 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16526 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–2010–N–0622]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification Requests and Recordkeeping

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.