FDA finds that the holders of the ANDAs listed in table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98 and section 505(k) of the FD&C Act (21 U.S.C. 355). Furthermore, the holders of the ANDAs listed in table 1 have failed to receive approval of a REMS for their products in accordance with section 505–1 of the FD&C Act. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived their opportunity for a hearing and any contentions concerning the legal status of the drug products. Therefore, based on these findings and pursuant to the authority under section 505(e) of the FD&C Act, approval of the ANDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of April 9, 2021.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07335 Filed 4–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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: Submit written comments (including recommendations) on the collection of information by May 10, 2021.

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 0910–0249. 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.

FDA Recall Regulations—21 CFR Part 7

OMB Control Number 0910–0249—Extension

This information collection helps support implementation of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) pertaining to product recalls, and regulations in part 7 (21 CFR part 7), subpart C promulgated to clarify and explain associated practices and procedures. Sections 7.49, 7.50, and 7.59 (21 CFR 7.49, 7.50, and 7.59) apply specifically to product recalls, which may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Agency. Recalls are terminated when all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. The regulations also provide for corrective actions to be taken regarding violative products and establish specific requirements that enable us to monitor and assess the adequacy of a firm's efforts in this regard. The provisions include reporting to FDA on the initiation and termination of a recall, as well as submitting recall status reports and making required communication disclosures. Specific guidance regarding recalls is set forth in § 7.59, although product-specific guidance documents may also be developed to assist respondents to the information collection. Agency guidance documents are issued in accordance with our good guidance regulations in 21 CFR 10.115, which provide for public comment at any time.

Consistent with § 7.50, all recalls monitored by FDA are included in an ''Enforcement Report'' once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Recall data in the Enforcement Report can be accessed through the weekly report publication, the quick and advanced search functionalities, and an Application Programming Interface (API). Instructions for navigating the report, accessing and using the API, and definitions of the report contents are found at *https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions.*

In the **Federal Register** of January 8, 2021 (86 FR 1508), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the 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
Firm initiated recall; § 7.46	2,779	1	2,779	25	69,475
Termination of recall; § 7.55	2,095	1	2,095	10	20,950
Recall status reports; § 7.53	2,779	13	36,127	10	361,270
Total			41,001		451,695

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

A review of Agency data shows that 8,337 recalls were conducted during fiscal years 2017 through 2019, for an average of 2,779 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 69,475 hours. Similarly, during the same period, 6,287 recalls were terminated,

for an average of 2,095 recall terminations annually, and we assume an average of 10 hours is needed for the corresponding information collection activity. To determine burden associated with recall status reports we divided the average number of annual submissions (36,127) by the average number of annual respondents (2,779) and assume 10 hours is necessary for the corresponding information collection, resulting in 361,270 hours annually.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications; § 7.49	2,779	445	1,236,655	0.05 (3 minutes)	61,832.75

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

To determine burden associated with recall communication disclosures described in § 7.49, we calculated an average of 445 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 61,832.75 burden hours annually.

These estimates reflect an overall decrease in the average number of annual responses by 245,846 and a decrease in the average number of annual burden hours by 70,949.25 since our last submission for OMB review and approval of the information collection.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07287 Filed 4–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Virtual Stakeholder Listening Session in Preparation for the 74th World Health Assembly

Subject: Office of Global Affairs: Virtual Stakeholder Listening Session in preparation for the 74th World Health Assembly.

Time and date: The session will be held on Thursday, May 13, 2021, from 10:00 a.m.–12:00 p.m. Eastern Time (ET).

Place: The session will be held virtually, and registration is required. Please RSVP by April 29, 2021 by sending your full name, email address, and organization to *OGA.RSVP@hhs.gov.* OGA encourages early registration.

Status: Open, but requiring RSVP to *OGA.RSVP@hhs.gov* to register.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 74th World Health Assembly—will hold an informal Stakeholder Listening Session on Thursday, May 13, 10:00 a.m.–12:00 p.m. ET. The listening session will be held virtually, and the meeting link will be shared with registered participants prior to the session.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation to the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 74th World Health Assembly. Your input will contribute to U.S. positions as we negotiate these important health topics with our international colleagues.

The listening session will be organized by agenda item, and participation is welcome from stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 74th World Health Assembly can be found at this website: *https://apps.who.int/gb/e/e_wha74.html.*

RSVP: Registration is required for the event. Please send your full name, email address, and organization to *OGA.RSVP@hhs.gov* to register. Please RSVP no later than Thursday, April 29, 2021.

Written comments are welcome and encouraged, even if you are planning on attending the virtual session. Please send written comments to the email address: *OGA.RSVP@hhs.gov.*

We look forward to hearing your comments related to the 74th World Health Assembly agenda items.

Dated: March 31, 2021.

Loyce Pace,

Director, Office of Global Affairs.

[FR Doc. 2021–07299 Filed 4–8–21; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request—60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 8, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Components Study of REAL Essential Curriculum.

Type of Collection: New.