requests an exemption and provides assurances, as required under § 106.121, that changes made by the manufacturer to an existing infant formula are limited to changing the type of packaging. A manufacturer may also be exempt from this requirement under § 106.100(g)(2), if the manufacturer requests an exemption and provides assurances, as required under § 106.121, that demonstrate to FDA's satisfaction that the change to an existing formula does not affect the bioavailability of the protein. Finally, a manufacturer of infant formula may be exempt from this requirement under § 106.96(g)(3) if the manufacturer requests an exemption and provides assurances, as required under § 106.121(i), that demonstrate that an alternative method to the PER that is based on sound scientific principles is available to show that the formula supports the quality factor for the biological quality of the protein. We estimate that the infant formula industry submits a total of 35 PER submissions: 34 exemption requests and the results of 1 PER study.

A PER study conducted according to the Association of Analytical Communities Official Method 960.48 is 28 days in duration. We estimate that there will be 10 rats in the control and test groups (20 rats total) and that food consumption and body weight will be measured at day 0 and at 7-day intervals during the 28-day study period (a total of 5 records per rat). We further estimate that measuring and recording food consumption and body weight will take 5 minutes per rat. Therefore, 20 rats × 5 records = 100 records; 100 records × 0.08 hour minutes per record = 8 hours to fulfill the requirements of § 106.96(f). Further, we estimate that a report based on the PER study will be generated and that this study report will take a senior scientist 1 hour to generate. Therefore, a total of 9 hours will be required to fulfill the requirements for § 106.96(f): 8 hours for the PER study and data collection, and 1 hour for the development of a report based on the PER study, as shown in rows 25 and 26 of table 2.

We estimate that five firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100 and that three firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3). Thus, the total recordkeeping burden is 40,232 hours.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Nutrient labeling; 21 CFR 107.10(a) and 107.20	5	13	65	8	520

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

We estimate compliance with our labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by five manufacturers.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07147 Filed 4–6–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–0075; FDA–2011–N–0015; FDA–2011–N–0076; FDA–2017–N–0932; FDA–2016–N–4487; FDA–2014–N–0345; FDA–2013–N–0523; FDA–2017–N–2428; FDA–2008–N–0312; and FDA–2014–N–1072]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Good Laboratory Practice Regulations for Nonclinical Studies	0910–0119	1/31/2021
Orphan Drug Designation Request Form and The Common European Medicines Agency/Food and Drug Administration Form for Orphan Medicinal Product Designation	0910–0167	1/31/2021
Electronic Records: Electronic Signatures	0910–0303	1/31/2021
Experimental Study on Warning Statements for Cigarette Graphic Health Warnings	0910–0848	1/31/2021

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB Control No.	Date approval expires
Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion	0910–0849	1/31/2021
Data to Support Drug Product Communications	0910–0695	2/28/2021
Applications for FDA Approval to Market a New Drug	0910–0001	3/31/2021
Animal Drug Adverse Event Reporting and Recordkeeping	0910–0284	3/31/2021
Extralabel Drug Use in Animals	0910–0325	3/31/2021
Application for Participation in FDA Fellowship Programs	0910–0780	3/31/2021

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07146 Filed 4–6–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0610]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

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: Fax written comments on the collection of information by May 9, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0701. 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.

Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

OMB Control Number 0910–0701—Extension

This information collection supports the above captioned Agency guidance. The guidance includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) Maintain documentation of the conditions that prevent them from meeting normal reporting requirements; (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored; and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the guidance, we estimate that approximately 5,000 firms will add the following to their COOP: (1) Instructions for reporting adverse events and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records.

In the **Federal Register** of October 31, 2017 (82 FR 50431) we published a notice inviting public comment of the proposed collection of information. Although one comment was received, it did not respond to any of the four information collection topics solicited in the notice under the PRA. We therefore made no changes to our estimate of the burden for the information collection, which remains as follows: