

Commissioner. The Division is supported by two branches: The *Technical Services* branch and the *Systems Management* branch. The Division provides assistance to states/tribes in developing or modifying automation plans to conform to federal requirements. It monitors approved state and tribal systems development activities; certifies state and tribal-wide automated systems; conducts periodic reviews to assure state and tribal compliance with regulatory requirements applicable to automated systems supported by Federal Financial Participation. It provides guidance to states and tribes on functional requirements for these automated information systems, and works with federal, state, local, and tribal health and human services agencies to foster and promote interoperability and collaboration across the automated systems that support their programs. It promotes interstate and tribal transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems and technology.

II. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

III. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

IV. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Dated: September 26, 2013.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0545]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

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 November 1, 2013.

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 aira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0256 and title "Infant Formula Requirements." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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.

Infant Formula Requirements—21 CFR Parts 106 and 107 (OMB Control Number 0910-0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when a batch of infant formula that has left the

manufacturers' control may be adulterated or misbranded, and keep records of distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

In a notice of proposed rulemaking published in the **Federal Register** of July 9, 1996 (61 FR 36154), we proposed changes in our infant formula regulations, including some of those listed in tables 1, 2, and 3 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the **Federal Register** of April 28, 2003 (68 FR 22341) (the 2003 reopening), FDA reopened the comment period for the proposed rule. Interested persons were originally given until June 27, 2003, to comment on these issues and the 1996 proposal. However, in response to a request, the comment period was extended to August 26, 2003 (68 FR 38247, June 27, 2003). FDA again reopened the comment period on August 1, 2006 (71 FR 43392) (the 2006 reopening) for 45 days to accept comment on a limited set of issues. In a notice of proposed rulemaking published in the **Federal Register** of April 16, 2013 (78 FR 22442), we proposed to amend our regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula. The document also included revised burden estimates for the proposed changes and solicited public comment. In the interim, FDA is seeking an extension of OMB approval for the current regulations so that we can continue to collect information while the proposals are pending. Accordingly, in the **Federal Register** of May 16, 2013 (78 FR 28854), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 412(d) of the FD&C Act	5	13	65	10	650
21 CFR 106.120(b)	1	1	1	4	4
21 CFR 107.50(b)(3) and (b)(4)	3	2	6	4	24
21 CFR 107.50(e)(2)	1	1	1	4	4
Total					682

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
106.100	5	10	50	400	20,000
107.50(c)(3)	3	10	30	300	9,000
Total					29,000

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

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
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.

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

We estimate that we will receive 13 reports from 5 manufacturers annually under section 412(d) of the FD&C Act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. We also estimate that we will receive one notification under § 106.120(b). The notification is expected to take four hours per response, for a total of four hours.

For exempt infant formula, we estimate that we will receive 2 reports from 3 manufacturers annually under §§ 107.50(b)(3) and (b)(4), for a total annual response of 6 reports. Each report is estimated to take 4 hours per response for a total of 24 hours. We also estimate that we will receive one notification annually under § 107.50(e)(2) and that the notification will take 4 hours to prepare.

We estimate that 5 firms will expend approximately 20,000 hours per year to

fully satisfy the recordkeeping requirements in § 106.100 and that 3 firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3).

We estimate compliance with our labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by 5 manufacturers.

Dated: September 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 13, 2013, between approximately 12:30 p.m. and 3:45 p.m.

Location: Rockwall II, Conference Room 1033, 5515 Security Lane, Rockville, MD 20852. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room.

Contact Person for More Information: Donald W. Jehn or Denise Royster, Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting