EARS; and solicit users for feedback for future upgrades and enhancements.

There is no cost to respondents to participate in this program. The total estimated annualized burden for this data collection is 25 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Users	150	1	10/60

Dated: August 4, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–19702 Filed 8–9–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

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 September 9, 2010.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 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 act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the 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), FDA proposed changes in the 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 interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

In the **Federal Register** of May 4, 2010 (75 FR 23777), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 412(d) of the 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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	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	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
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, FDA consulted its records of the number of infant formula submissions received in the past. All infant formula submissions to FDA may be provided in electronic format. The hours per response reporting estimates are based on FDA's experience with similar programs and information received from industry.

FDA estimates that it will receive 13 reports from 5 manufacturers annually under section 412(d) of the 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. FDA also estimates that it will receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, FDA estimates that it 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. FDA also estimates that it will receive one notification under § 107.50(e)(2). The notification is expected to take four hours per response, for a total of four hours.

FDA estimates that 5 firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100. It is estimated that 3 firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3).

FDA estimates that compliance with the labeling requirements of §§ 107.10(a) and 107.20 will require 520 hours annually by 5 manufacturers.

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19640 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–P–0218]

Determination That DECA-DURABOLIN (Nandrolone Decanoate) Injection, 200 Milligrams/Milliliter, 1 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 milligrams/milliliter (mg/mL), 1 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nandrolone decanoate, 200 mg/mL, 1 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DECA-DURABOLIN (nandrolone decanoate) Injection is the subject of NDA 13–132, held by Organon, Inc.