of each such program and each pregnancy success rate which the program failed to report.

This Announcement includes information on the change in the data collection contractor and the change in the approved data reporting system for the 2004, 2005, 2006, 2007, and 2008 ART data reporting years in accordance with the FCSRCA. This Announcement supplements the September 1, 2000 and the February 5, 2004, notices.

**SUPPLEMENTARY INFORMATION:** CDC has contracted with Westat to develop a data reporting system and to collect annual clinic-specific and cycle-specific data from all practicing assisted reproductive technology clinics in the U.S. and its territories for the 2004, 2005, 2006, 2007, and 2008 ART data reporting years. The contract covers clinic tracking, data collection and quality assurance, and validation activities. As such, Westat is the new contractor for ART data collection for the 2004 through 2008 ART data reporting years.

The new Web-based data reporting system (developed by Westat) for the 2004, 2005, 2006, 2007, and 2008 ART data reporting years will be called the National ART Surveillance System (NASS). As such, NASS will be the only approved data reporting system for 2004 through 2008 ART data submissions. ART programs should be aware that Westat will develop and provide all necessary instruction materials for extracting and importing data from other electronic medical record systems into NASS and for checking imported data to ensure that it retains the accuracy and compatibility of the data entry system from which it was extracted.

The anticipated deadline for reporting is December 15 of the year 1 year subsequent to the reporting year in question. (For example, the anticipated deadline to report data on cycles initiated in 2004 is December 15, 2005.) An ART program will not be considered to be in compliance with the federal reporting requirements of FCSRCA if the ART program was in operation in the full year that is being reported, *i.e.*, the clinic was in operation after January 1 of the reporting year, and fails to submit a dataset to Westat in the required data reporting system (NASS) by the reporting deadline. ART programs considered to not be compliant with the federal reporting requirements of FCSRCA will be listed as non-reporters in the published report.

The data reporting activities and the amount and type of data collected will be similar to the current system requirements outlined in the September 1, 2000 **Federal Register** notice (Volume 65, No. 171, pages 53310–53316). CDC has completely funded the data reporting activities for the 2004 through 2008 reporting years. Thus, ART programs will not be charged fees to obtain the new reporting system or to submit data using the new reporting system.

Validation activities for the 2004 through 2008 data reporting years will be similar to those described in the September 1, 2000 **Federal Register** notice (Volume 65, No. 171, pages 53310–53316). Westat will provide the necessary personnel to perform the validation site visits.

Each ART program should be aware that the Paperwork Reduction Act is applicable to this data collection. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees, unless the agency has submitted a Standard Form 83, Clearance Request, to the Director of the Office of Management and Budget (OMB), and OMB has approved the collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. CDC has obtained OMB approval to collect this data under OMB control No. 0920–0556.

CDC will continue to provide information to all ART programs regarding data collection activities as information becomes available.

**FOR FURTHER INFORMATION CONTACT:** Victoria Wright, Assisted Reproductive Technology Epidemiology Unit at (770) 488–6384.

Dated: January 25, 2005.

**James D. Seligman,**

*Associate Director for Program Services, Centers for Disease Control and Prevention.*

[FR Doc. 05–1787 Filed 1–31–05; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005N–0029]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Recall Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements related to the recall of infant formula.

**DATES:** Submit written or electronic comments on the collection of information by April 4, 2005.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, 107.280 (OMB Control Number 0910–0188)—Extension**

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107 (21 CFR part 107), subpart E) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 107.230 | 2 | 1 | 2 | 4,500 | 9,000 |
| 107.240 | 2 | 1 | 2 | 1,482 | 2,964 |
| 107.250 | 2 | 1 | 2 | 120 | 240 |
| 107.260 | 1 | 1 | 1 | 650 | 650 |
| Total | | | | | 12,854 |

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

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years.

Dated: January 25, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign