

c. To characterize the reasons that males do not accept urine-based testing for Ct.

d. To identify other settings in which males would avail themselves of urine testing for Ct.

3. Objectives Related to Feasibility

a. To measure the proportion of tested males who return or otherwise learn their test results.

b. To determine the proportion of infected males who receive treatment.

c. To measure the median time until patients return for their test results.

d. To determine how many female sex partners infected males identify/name/notify.

e. To measure the characteristics of identified, named, and located partners.

f. To measure the infection rate among located partners.

g. To determine the proportion of located female sex partners who were notified by their male partner.

h. To determine if screened males access other sites where they could be screened.

i. To determine which strategies or approaches enhance completeness of timely treatment of infected men.

4. Objectives Related to Cost Estimates

a. To measure the cost to detect and treat an infected asymptomatic male.

b. To measure the costs of partner services associated with finding and treating the female sex partners of an asymptomatic infected male?

c. To measure the overall cost to identify an infected female using male screening.

5. Objectives Requiring Longitudinal Follow Up

a. To determine whether a positive screening test influences a man's intended future sexual behavior (including condom use, partner selection, partner number, health seeking behavior).

b. To determine the proportion of treated males who are re-infected at defined intervals after initial screening.

c. To ascertain how many males report that their partner has been treated at a follow up visit.

[FR Doc. 99-12313 Filed 5-14-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99049]

National Sexual Violence Resource Center (NSVRC) Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 1999 funds to establish a National Sexual Violence Resource Center was published in the **Federal Register** on May 4, 1999, [Vol. 64, No. 85, Pages 23839-23842]. The notice is amended as follows:

On page 2389, Third Column, Under Section D. Program Requirements, Item No. 8, change to read: Provide a detailed evaluation plan that will document program process, effectiveness, impact, and outcomes.

Dated: May 11, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-12311 Filed 5-14-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0192]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Infant Formula Recall Regulations and Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA). In addition, this notice is correcting the title of the information collection. In the **Federal Register** of February 23, 1999 (64 FR 8832 at 8833), the title of the information collection was incorrectly listed as a "Reinstatement;" it should have been listed as an "Extension." This document corrects that error.

DATES: Submit written comments on the collection of information by June 16, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed

collection of information to OMB for review and clearance.

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, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to: (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: (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. If manufacturers were not required to provide this information to FDA, FDA's

ability to ensure that recalls are conducted properly would be greatly impaired.

In the **Federal Register** of February 23, 1999 (64 FR 8832), the agency requested comments on the proposed collections of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|---------------------|
| 107.230 | 3 | 1 | 3 | 4,500 | 13,500 |
| 107.240 | 3 | 1 | 3 | 1,482 | 4,446 |
| 107.250 | 3 | 1 | 3 | 120 | 360 |
| 107.260 | 3 | 1 | 1 | 650 | 650 |
| Total | | | | | 18,956 ² |

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

²Due to clerical error, the reporting burden hours for §§ 107.230, 107.240, 107.250, and the total burden hours that appeared in a notice issued in the FEDERAL REGISTER of February 23, 1999 (64 FR 8832), were incorrect. Table 1 of this document contains the correct estimates.

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 three recalls in the last 3 years, or one recall annually.

Dated: May 10, 1999.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 99-12283 Filed 5-14-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Innovative Food Safety Projects; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations, is announcing the availability of grant funds for the support of innovative food safety pilot programs. Approximately \$300,000 will be available in fiscal year 1999. FDA anticipates making six to eight awards, not to exceed \$50,000 (direct and indirect costs combined) per award. Support of these grants will be for 1 year. The number of grants funded will depend on the quality of the applications received and the availability of Federal funds to support the grant. This is a pilot grant program which, if successful, may lead to other grant programs in the future. These grants are not intended to fund or conduct food inspections.

DATES: Submit applications by July 1, 1999. If the closing date falls on a weekend or on a holiday, the date of submission will be extended to the following workday.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Robert L. Robins, Chief Grants Management Officer, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301-827-7185, e-mail "rrobins@oc.fda.gov". (Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.)

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Richard H. Barnes or Glenn Johnson, Division of Federal-State Relations, Office of Regulatory Affairs, Food and Drug Administration (HFC-150), 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, 301-827-6906, Internet site: "www.fda.gov/ora/fed-state".

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA will support projects covered by this notice under section 1701 (300u) of the Public Health Service Act (42 U.S.C. 241). FDA's project program is described in the Catalog of Federal Domestic Assistance, No. 93-245, and applicants are limited to food safety regulatory agencies of State and local governments. The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, stock No. 017-0010-0474-0) through Superintendent of Documents, Government Printing Office,