

adequate to measure differences when warranted, and (d) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing collaborative relationships with community(ies) and recognition of mutual benefits.

4. Evaluation (30 Percent)

The extent to which the proposed evaluation plan is detailed and capable of documenting program process and outcome measures, including benefit/cost analysis, risk assessment, and risk management (applicants may wish to refer to A Framework for Assessing the Effectiveness of Disease and Injury Prevention, MMWR, March 27, 1992/ Vol.41/No. RR-3 for further information on this methodology). You may access this document on CDC's Web page at www2.cdc.gov/mmwr/mmwrscrch.htm. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, and capacity to perform the evaluation.

5. Staff, and Resources (20 Percent)

Providing for a full-time director/coordinator and staff who have authority, responsibility, and expertise to carry out the project. The extent to which the applicant can provide adequate facilities, staff and/or collaborators, and resources to accomplish the proposed goal(s) and objectives during the project period. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, previous experience, broad experience in risk assessment and analysis and capacity to perform the undertaking successfully.

6. Budget and Justification (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities.

7. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. semiannual progress reports
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum I.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2000
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301, 317(k)(2), 391, 392, and 394 of the Public Health Service Act, [42 U.S.C. section 241, 247b(k)(2), 280b, 280b-1, and 280b-2], as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC home page www.cdc.gov on the Internet (click on funding).

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

For business management technical assistance, contact: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99123, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, telephone (770) 488-2717, Email address: jcw6@cdc.gov

For program technical assistance, contact: Bruce Jones, M.D., Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention, 4770 Buford Hwy., N.E., Mailstop K63, Atlanta, GA 30341-3724, telephone: 770 488-4545, email address: bdj2@cdc.gov

Dated: May 11, 1999.

John L. Williams,

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

[FR Doc. 99-12312 Filed 5-14-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99104]

Notice of Availability of Funds; Innovative Demonstration Projects to Screen and Treat Asymptomatic Males for Chlamydia Trachomatis Infection Using Urine-Based Diagnostic Tests: Translational Research

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program to conduct innovative demonstration projects using nucleic acid amplification tests on urine specimens to screen and treat asymptomatic males with Chlamydia Trachomatis (CT)infection. This program addresses the "Healthy People 2000" priority area of Sexually Transmitted Diseases. The purpose of the program is to determine the acceptability, feasibility, and cost associated with different approaches to screening asymptomatic males for CT infection. Successful applicants will implement demonstration projects using nucleic acid amplification tests on urine specimens to screen asymptomatic males for CT infection and will conduct research in the context of the demonstration project. Please reference Appendix 1 for background information relevant to this program announcement. Appendix 2 outlines project objectives.

B. Eligible Applicants

Applications may be submitted by public and private non-profit organizations in partnership with State or local health departments. Any organization may be the primary applicant, but each application must include both an agency/institution with program implementation experience and an agency/institution with research experience. All applications must include a partnership with a State or local health department.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible

to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$750,000 is available in FY 1999 to fund two to three awards, with an average yearly award of 250,000, ranging from \$200,000 to \$300,000. It is expected that the awards will begin on or about September 30, 1999, and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds awarded under this program may not be used for treatment.

Funding Preferences

Funding preference may be given to applicants to achieve geographic balance.

D. Program Requirements

Recipients will work with CDC to assure a scientifically sound demonstration project and embedded research study. If multiple awards are made, the only requirement for uniformity of approach across sites will relate to collection of a core set of data elements (including those related to cost) to allow systematic comparisons between different approaches to male screening.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under the subparagraph Recipient Activities and CDC will be responsible for the activities listed under the subparagraph CDC Activities.

1. Recipient Activities

a. Design and implement a demonstration project to screen asymptomatic males for chlamydia infection which addresses as many of the objectives listed in Appendix 2 as possible. At a minimum, recipients should gather routine data that will permit measurement of the prevalence of infection and male treatment rates, as well as the cost to detect and treat an infected male, and his infected female partners. Recipients are encouraged to screen in settings other than a sexually transmitted diseases clinic; however, a sexually transmitted diseases clinic could be one of several settings where screening is conducted, as this could provide a useful comparison to other

screening venues developed by the recipient.

b. Design and implement a research study that can be embedded within the male CT screening demonstration project and which entails longitudinal follow up of a subset of men in order to address as many of the Appendix 2 objectives requiring longitudinal follow up as possible (i.e., reinfection, notification of female partners, reported behavior change after learning a positive test result).

c. Collaborate with other recipients in developing and collecting a common set of core variables to permit systematic comparison between different approaches (for the purpose of cost comparisons, this will require measurement of all relevant costs, including providers' costs of service delivery and participants' costs).

d. Collaborate with other recipients during implementation of the demonstration project and research study. Collaboration will include (1) communication with CDC regarding project and study progress and (2) participation in quality control procedures, and in regularly scheduled meetings and conference calls with CDC.

e. Recipients will use findings from their own demonstration project/ embedded research to develop at least one publication for a peer-reviewed journal.

f. Submit and receive approval of study protocol by the recipient's local institutional human investigation review board (IRB).

2. CDC Activities

a. Provide technical assistance and scientific expertise. CDC staff will provide current scientific and programmatic information relevant to the design and conduct of the demonstration project and embedded research study.

b. As needed, provide technical advice to awardees in developing and collecting a common set of core variables to enable comparisons between different approaches, including those needed to accurately and completely measure costs, and which would allow for cross-site comparisons that could include a cost effectiveness analysis. Collaborative activities may include technical advice on awardee-development of common data collection instruments. As needed, CDC may assume responsibility for developing a centralized system for data management for the core set of data elements collected by each of the funded projects.

c. Assist in analysis and dissemination of results; as needed,

assist each site in analyzing data and in dissemination of study results.

d. Monitor and Evaluate Scientific and Operational Accomplishments of the Project: This will be accomplished through periodic site visits, telephone calls, and review of technical reports and interim data analysis.

e. Submit and receive approval of study protocol by the Centers for Disease Control and Prevention IRB. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 double-spaced pages, printed on one side, with one inch margins, and size 12 font. Appendices may include letters of support, data tables, and bibliography only.

F. Submission and Deadline

Letter of Intent (LOI)

A letter of intent must be submitted on or before June 14, 1999 to the Grants Management Specialist listed in the "Where to Obtain Additional Information" section of this announcement. No applications will be accepted without a letter of intent. Letters of intent must be no more than one page, must be prepared with a Courier 12-point font and must include the following: statement of intent to apply, reference to Program Announcement 99104, title of the proposed project and the names, phone numbers, and email addresses for the lead investigators representing each collaborating institution or agency.

Application

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before August 2, 1999 submit the application to the Grants Management Specialist listed in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either received on or before the deadline date or sent on or before the deadline date and received in time for independent review. (Applicants must

request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.) Applications that do not meet these criteria will not be considered and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Background and Rationale for the Male Screening Demonstration Project and Embedded Research Study (10 Points)

Degree to which the applicant (a) Describes the local prevalence of CT infection (with stratification by age, gender, and ethnicity); (b) demonstrates knowledge of the medical/public health literature describing urine testing to identify asymptomatic men infected with CT; (c) demonstrates insight into factors that could influence the effectiveness of a male screening strategy for primary prevention among women; (d) demonstrates insight into the logistic and ethical challenges of offering diagnostic testing to an asymptomatic population in non-traditional and non-clinical settings; (e) presents a compelling rationale for their proposed approach to screening asymptomatic males for Chlamydia infection; (f) provides data to support their choice of screening venues; (g) describes any previous or existing male screening programs in their locality and describes how the proposed demonstration project compares to any existing local male screening programs, and (h) presents a rationale for their selection of research objectives from among those in Appendix 2.

2. Objectives (5 Points)

Extent to which the application addresses the research objectives outlined in Appendix 2 of this program announcement.

3. Demonstration Project Activities (20 Points)

Extent to which the application describes the proposed activities with detailed plans for implementation of the demonstration project, including: (a) A detailed and realistic time line for the specified activities; (b) specific information on the site where screening will be conducted, hours that screening will be offered, staffing, provisions for urine specimen collection (e.g., restrooms convenient to the site where

males are being invited for screening, adherence to CLIA (Clinical Laboratory Improvement Amendments) requirements for specimen collection); (c) plans for obtaining informed consent (if needed); (d) plans for males to learn test results and receive treatment; and (e) plans to seek, screen, and treat the female sex partners of infected males.

4. Potential Influence of the Demonstration Project on Public Health Practice (15 Points)

Extent to which the applicant presents a detailed and logical plan for conducting a screening program that will provide access to a male population with a high prevalence of CT infection; particularly males who may contribute disproportionately to infecting females. Points will also be given for the extent to which the study population is representative of a large pool of potentially infected men and the likelihood that such a population could be identified and accessed in other locations across the United States. Points will be awarded to applicants describing a demonstration project that could be incorporated into the array of public health activities with a minimum of additional training, resources, and infrastructure. Points will also be awarded to applications that describe a plan for integrating partner services into the demonstration project.

5. Design of Research Study Requiring Longitudinal Follow Up (20 Points)

Extent to which the embedded research study is (a) both an appropriate and optimal means of addressing research objectives in Appendix 2 that require longitudinal follow up; (b) will achieve the research objectives without interfering with assessments of acceptability and feasibility (which could be biased if measured in study subjects consenting to participate in a study requiring longitudinal follow up); (c) includes clear and valid calculations for the sample sizes that would be required to measure effects related to each of the applicants chief research objectives; (d) provides clear description of appropriate comparison groups in each aspect of the study; and (e) if the study includes adolescents, displays familiarity with the legal and ethical issues surrounding elicitation of information regarding sexual activity between adolescents and older sex partners, (including the particulars of relevant State legislation), and demonstrates a means of adhering to such legislation in the proposed study.

6. Program and Research Capacity (25 Points)

The overall ability of the applicant to perform the technical aspects of the project. The quality of the applicant's: (a) Proposed collaboration with State or local health departments and partners for either research or program implementation (including letters of support); (b) availability and identification of personnel with the needed experience and competence in community outreach and program implementation, sexually transmitted disease service delivery, partner services, study design and conduct, data collection, analysis, and dissemination; (c) assurance that staff can be hired within an appropriate amount of time; (d) ability and willingness to collaborate in the development and collection of a common set of variables to permit cross-site comparisons; (e) demonstration of access to the data needed to permit true costs of service delivery to be determined so that a cost effectiveness evaluation can be done, e.g., demonstration of the ability to identify and collect data to measure the costs for screening that include testing and treatment costs, provider costs for wages and overhead, and participants' travel and time costs, as well as costs for partner services; (f) documentation of the availability of adequate laboratory, clinical, and administrative facilities and resources to conduct the proposed research, including a letter of agreement from the laboratory that will be conducting nucleic acid amplification testing on urine specimens and a letter of agreement from the administrative or managerial director of the proposed screening site (and board of directors or community board if appropriate); (g) access to cost-efficient, locally available staff to complete data entry and data management.

7. The Degree to Which the Applicant Has Met the CDC Policy Requirements Regarding the Inclusion of Ethnic and Racial Groups in the Proposed Research. (5 Points)

This includes:

1. The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation.
2. The proposed justification when representation is limited or absent.
3. A statement as to whether the design of the study is adequate to measure differences when warranted.
4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with

community(ies) and recognition of mutual benefits.

5. This program specifically seeks applications describing male screening programs, with a long term objective to develop strategies that can increase public health capacity to detect and treat infected females. Applicants need not address the inclusion of women in their response to evaluation criterion 7.

8. Budget (Not Scored)

The budget should anticipate the salaries of appropriate staff, travel for principal investigator and project supervisor to meet with CDC annually, supplemental needs related to diagnosis, management, and treatment of CT and other concurrently diagnosed STDs, including anticipated partner tracing activities, longitudinal participation, and other needs. The applicant should provide a line-item first year budget (with a budget narrative that justifies each line item). Budgets will be evaluated on the appropriateness of budget estimates in relation to the proposed research, and the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

9. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements
For Award Recipients Provide CDC with original plus two copies of

1. Semi-annual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist listed in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-6 Patient Care
- AR-7 Executive Order 12372 Review
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements

- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2000
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317 of the Public Health Service Act [42 U.S.C. 241 and 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.978.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest. If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Curtis Meusel, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99104, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E15, Atlanta, Georgia 30341, Telephone (770) 488-2738, Email address CTM6@CDC.GOV.

Complete application information is also available on the CDC home page on the Internet: [HTTP://WWW.CDC.GOV](http://WWW.CDC.GOV)

For program technical assistance, contact: Julie Schillinger, MD, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Mail Stop E02, Atlanta, GA 30333, Telephone: (404) 639-8368, Email: jus8@cdc.gov.

Dated: May 11, 1999.

John L. Williams,

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

Appendix 1—Background

The bulk of the morbidity associated with CT infection appears to be borne by women, in whom infection can lead to pelvic inflammatory disease with subsequent infertility, ectopic pregnancy, and chronic pelvic pain. Women with CT infection have an associated increased risk for acquisition of HIV, and are at an increased risk for adverse outcomes of pregnancy (low birth weight, prematurity); there is also an increased risk for morbidity among infants born to infected mothers (neonatal pneumonia and ocular infections). For these reasons, efforts to reduce the morbidity associated with CT infection have focused on identifying and treating infected women, relying largely on widespread screening of asymptomatic women, with subsequent treatment of infected women and, to a lesser extent, their infected sexual partners. Regions of the

country with active chlamydia prevention programs have demonstrated reductions of 36-59% in the measured prevalence of infection among women served in specific settings. There remains, however, substantial variation in CT-prevalence measured in different regions of the U.S., and it is not clear what strategies would be most effective in reducing disease below the threshold (3.9-7%) achieved in regions with aggressive prevention programs.

The application of nucleic acid amplification technology to the development of a urine-based diagnostic test for CT infection has broadened the potential for conducting screening of asymptomatic women, and, for the first time, presents a feasible means of screening asymptomatic men. Although urine-based diagnostic tests have been approved for use in men and are being used in select settings, because available data suggest that severe sequelae of Ct infection are relatively infrequent in men, several important questions must be answered before national chlamydia control efforts and resources are directed to widespread screening for men. First, what approaches to male screening for CT infection are most acceptable and feasible, and second, is male screening an effective means of reducing disease in women? To address these questions it will be necessary to explore the prevalence of infection in different asymptomatic male populations which may be accessed by urine screening, to determine the acceptability and feasibility of screening these populations, and to measure the cost of detecting and treating an infected male and his infected female sex partners. To evaluate the comparative value of different approaches to screening asymptomatic males, screening would need to be conducted in a variety of different venues, including sexually transmitted diseases clinics. Ultimately, the value of screening males for CT infection must be measured against the alternative of using the same resources to screen women. Research to further knowledge of reinfection rates among males, changes in sexual behavior resulting from diagnosis with asymptomatic CT infection, and men's willingness to name and assist in locating female sex partners will be useful in interpreting the value of male screening.

Appendix 2—Research Objectives for Innovative Demonstration Projects and Embedded Research Studies

1. Objectives Related to Prevalence

- a. To measure the prevalence of CT infection among populations of males accessible with urine-based screening programs.
- b. To determine whether there is a trend in prevalence over the study period (are infections accessible to screening programs exhausted over a short time period?).
- c. To identify predictive characteristics of infected males.

2. Objectives Related to Acceptability

- a. To measure the proportion of males accepting urine-based testing.
- b. To measure the characteristics of males who refuse/accept screening.

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]

BILLING CODE 4163-18-P

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