Extension of deadlines: ACF may extend an application deadline for applicants affected by acts of God such as floods, hurricanes, or when there is widespread disruption of the mails, or when it is anticipated that many applications will come from rural or remote areas. A determination to waive or extend deadline requirements rests with the Chief Grants Management Officer.

E. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995, Public Law 104–13, the Department is required to submit to OMB for review and approval any reporting and record keeping requirements in regulations including program announcements. All information collections within this program announcement are approved under the following current valid OMB control numbers 0348–0043, 0348–0044, 0348–0040, 0348–0046, 0925–0418 and 0970–0139.

Public reporting burden for this collection is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

F. Required Notification of the State Single Point of Contact

This program is covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

• All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, American Samoa and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-four jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodate or explain rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, ACYF/Office of Grants Management, 330 C Street S.W., Washington, D.C. 20447, Attn: Head Start Partnerships with Tribally Controlled Land Grant Colleges and Universities. A list of the Single Points of Contact for each State and Territory can be found on the web site: http://www.hhs.gov/progorg/grantsnet/laws-reg/spoq0695.htm

Catalogue of Federal Domestic Assistance 93.600

Dated: February 17, 1999.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 99–4330 Filed 2–22–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0192]

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 comments on the collection of information by April 26, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: 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 below.

With respect to the following collection of information, FDA invites comments on: (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—Reinstatement)

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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	1	1	1	4,500	4,500
107.240	1	1	1	1,482	1,482
107.250	1	1	1	120	120
107.260	1	1	1	650	650
Total					6,752

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

Dated: February 8, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–4338 Filed 2–22–99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of Intent to Prepare a Comprehensive Conservation Plan and Associated National Environmental Policy Act Document for the San Joaquin River National Wildlife Refuge, Stanislaus and San Joaquin Counties, California.

SUMMARY: The Fish and Wildlife Service (Service) is preparing a Comprehensive Conservation Plan (CCP) and National Environmental Policy Act (NEPA) document for the San Joaquin River National Wildlife Refuge. This notice advises the public that the Service intends to gather information necessary to prepare a CCP and environmental documents pursuant to the National Wildlife Refuge System Administration Act of 1966, as amended, and NEPA. The public is invited to participate in the planning process. The Service is furnishing this notice in compliance with the Service CCP policy:

(1) To advise other agencies and the public of our intentions,