The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Dated: July 19, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–18925 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0296]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regulations Under the Federal Import Milk Act

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).

DATES: Submit written comments on the collection of information by August 25, 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: Wendy Taylor, 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.

Regulations Under the Federal Import Milk Act—21 CFR Part 1210 (OMB Control Number 0910–021)—Extension

Under the regulations (part 1210 (21 CFR part 1210)) implementing the Federal Import Milk Act (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F. In addition, the regulations require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address.

In the **Federal Register** of April 30, 1999 (64 FR 23333), 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 BURDEN[1]

Form	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	4	1	4	0.5	2.0
FDA 1993/Applicant of permit	1210.20	4	4	4	0.5	2.0
FDA 1994/Tuberculin test[2]	1210.13					
FDA 1995/Physical examination of cows[2]	1210.12					
FDA 1996/Sanitary inspection of dairy farms	1210.11	4	200[3]	800	1.5	1200.0
FDA 1997/Sanitary inspection of plants	1210.14	4	1	4	2.0	8.0
Total						1212.0

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

[2]No burden has been estimated for Forms FDA 1994 and 1995 because they are not currently being used.

[3]Due to a clerical error, the reporting burden hours for FDA 1996/Sanitary inspection of daily farms that appeared in a notice issued in the FEDERAL REGISTER of April 30, 1999 (64 FR 23333) were incorrect. Table 1 of this document contains the correct estimates.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	4	1	4	0.05	0.20

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

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). No burden has been estimated for Forms FDA 1994 and 1995 because they are not currently being used. The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign Government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Dated: July 19, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–18927 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition; Notice of Intent to Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to noncompetitively supplement the cooperative agreement with the University of Maryland, College Park (UMCP) for up to an estimated $2 million per annum. These funds will provide additional support to the UMCP's Joint Institute for Food Safety and Applied Nutrition (JIFSAN) for the purpose of addressing emerging health issues and crises that are related to food safety and applied nutrition and animal health sciences, and expanding the current scope to include other agency programs such as cosmetics.

DATES: Submit the application by August 25, 1999. If this date falls on a weekend, it will be extended to Monday; if this date falls on a holiday, it will be extended to the following workday.

ADDRESSES: An application is available from and should be submitted to: Maura C. Stephanos, Office of Regulatory Affairs Support and Assistance Management Branch (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183. If the application is hand carried or commercially delivered, it should be addressed to Maura C. Stephanos, 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Maura C. Stephanos (address above).

Regarding the programmatic aspects: Elizabeth M. Calvey, Center for Food Safety and Applied Nutrition (HFS–6), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4716.

SUPPLEMENTARY INFORMATION: This project is authorized under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). This activity is generally described in the Catalog of Federal Domestic Assistance at No. 93.103. The application will not be subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Program (45 CFR part 100).

I. Restricted Eligibility

In the **Federal Register** of May 22, 1997 (62 FR 28049), FDA announced that a single source application for a cooperative agreement to support the JIFSAN at the UMCP would be accepted. Supplemental funding referenced herein will provide for the implementation and enhancement of activities associated with the JIFSAN projects described and authorized under the original award (FD–U–001418–01) dated September 29, 1997.

II. Availability of Funds

FDA will provide supplemental funding up to an estimated $2 million per annum to the cooperative agreement, which is at a level greater than the 25 percent of the original award currently provided under agency policy. Supplemental funding will provide support of the JIFSAN programs primarily through available Food Safety Initiative funds and funds from other government agencies.

The original cooperative agreement was approved for 5 years of funding and currently has 3 years of noncompetitive support remaining, which is contingent upon the availability of fiscal year appropriations and successful performance. FDA anticipates that supplemental funding of the cooperative agreement will commence on or before September 30, 1999.

III. Background

JIFSAN was established between FDA and the UMCP in April 1996, through a formal Memorandum of Understanding (MOU), to create a partnership that allows for more efficient use of research resources, thereby enhancing overall public health by expanding and improving food safety and nutrition research as well as research in other program areas that impact on public health policy. As the role of FDA research scientists in regulatory activities increases (e.g., petition review, rulemaking, enforcement compliance standards, hazard analysis critical control point performance standards), it is vital that these same scientists have ready access to very specialized research facilities and expertise that are in close proximity to FDA's administrative offices. The unique needs for research in support of regulatory programs has been one of the key reasons for maintaining a strong FDA research program. JIFSAN is a jointly administered, multi-disciplinary research and outreach program. JIFSAN was established as part of FDA's consolidation project affecting FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine. The primary focus of JIFSAN is food safety and nutrition, specifically as related to risk analysis, applied microbiology, natural toxins, chemical contaminants, animal health sciences, and food composition and nutrition. JIFSAN also encompasses other agency programs such as cosmetics, dietary supplements, and food labeling.

IV. Purpose

Supplemental funding to FDA's current cooperative agreement will provide the UMCP with the necessary resources to conduct further research related to the goals of the National Food Safety Initiative and to leverage additional resources for applied nutrition, animal health science activities, and other agency programs. These resources would: (1) Expand the expertise for public health research and risk assessment initiatives, (2) support the Risk Assessment Consortium, and (3) increase innovative public/private research and education partnerships. Because international safety regulations must be founded on science-based risk assessments, FDA's scientists must have a lead role in their development.

Additionally, supplemental funding will provide resources to identify gaps in risk analysis to: (1) Minimize/reduce uncertainty in risk management decisions; (2) improve the quality of risk assessments applied to agency