• *Western Maine Centers for Children on behalf of Western Maine Access, Wilton, ME 04294*

Western Maine ACCESS Early Learning Opportunity Grant.

The geographic area served by this project is Androscoggin, Franklin, and Oxford Counties.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0075]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Administrative Detention and Banned Medical Devices

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.

DATES: Fax written comments on the collection of information by July 25, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Detention and Banned Medical Devices (OMB Control Number 0910–0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), to detain during establishment inspections devices that are believed to be adulterated or misbranded. FDA issued a final rule that published in the **Federal Register** of March 9, 1979 (44 FR 13234 at 13239), on administrative detention procedures, which includes, among other things, certain reporting requirements under § 800.55(g) and (k) (21 CFR 800.55(g) and (k)) and recordkeeping requirements. Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final rule for banned devices that published in the **Federal Register** of May 18, 1979 (44 FR 29214 at 29221), contained certain reporting requirements under §§ 895.21(d) and 895.22 (21 CFR 895.21(d) and 895.22). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner) decides to initiate a proceeding to make a device a banned device, a notice of proposed rulemaking will be published in the **Federal Register** and this document will contain the finding that the substantial risk of illness or injury exists. The document will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling or change of labeling, or change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

Respondents to this collection of information are those manufacturers, distributors, or importers whose products FDA seeks to detain or ban. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

In the **Federal Register** of March 17, 2003 (68 FR 12706), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for 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	Total Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22	26	1	26	16	416
Total					441

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
800.55(k)	1	1	1	20	20

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

Over the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, the Center for Devices and Radiological Health has had very few or no annual responses for this information collection and normally reports one response per year.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained.

Dated: June 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15995 Filed 6–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Security Research—Rapid Methods Development: Availability of Cooperative Agreements; Request for Applications; RFA–FDA–CFSAN–03–1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing the availability of approximately $3 million in research funds for fiscal year (FY) 2003. These funds will be used to support collaborative research efforts between CFSAN and scientists, and to complement and accelerate ongoing research in four project areas in order to reduce the incidence of foodborne illness and to ensure the integrity of the nation's food supply (including food additives and dietary supplements) and cosmetics. All awards will be subject to the availability of FY 2003 funds.

DATES: Submit applications by August 11, 2003.

ADDRESSES: Submit completed applications to: Rosemary Springer, Grants Management Specialist, Grants Management Staff (HFA–520), Division of Contracts and Procurement Management, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182, e-mail: rspringe@oc.fda.gov. Hand-carried or commercially delivered applications should be sent to: Food and Drug Administration, 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.

Application forms are available either from Rosemary Springer (see previous paragraph) or on the Internet at http://grants1.nih.gov/grants/funding/phs398/phs398.html. NOTE: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. Please note that FDA is unable to receive applications electronically.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Rosemary Springer (see **ADDRESSES** section).

Regarding the programmatic aspects of this notice: John W. Newland, Research Coordinator, Office of Science (HFS–006), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1915, e-mail: john.newland@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible and to protecting the integrity of the nation's food supply. Research in food safety seeks to reduce the incidence of foodborne illness by improving our ability to detect, characterize, and quantitate foodborne pathogens, toxins and chemicals that could jeopardize the safety and security of the food supply, and to find new and improved ways to control these agents. Since 1998, CFSAN has supported multiyear cooperative agreements intended to help achieve the research goals of reducing the incidence of foodborne illness and ensuring the integrity of foods, including food additives and dietary supplements, and cosmetics. This extramural program supports novel collaborative research efforts between CFSAN and scientists, and leverages expertise not found within CFSAN to complement and accelerate ongoing research. Collaborations such as these provide information critical to food safety guidance and policymaking, help address the needs of CFSAN regulatory programs, stimulate fruitful interactions between FDA scientists and those within the greater research community, and benefit the American public.

In continuation of this effort to help enhance the capabilities of the agency, CFSAN is announcing the availability of research funds for FY 2003 to support research in the following four categories: (1) Development of rapid analytical screening methods for the detection of pathogens that are not usually associated with food and foodborne illness at a contamination level of 100 to 10,000 microbial pathogens/gram (g) of food without pregrowth or selective enrichment; (2) development of PCR-based methods for rapid confirmatory identification of pathogens that are not usually associated with food and foodborne illness; (3) development of rapid screening methods capable of detecting a broad range of nontraditional chemical and toxin adulterants; and (4) development of improved equipment, software, procedures, and/or methods for determining radionuclide contamination in foods.

Approximately $3 million will be available in FY 2003. FDA anticipates making awards of $100,000 to $600,000 (direct plus indirect costs) per award. The research efforts supported by these agreements may be up to 3 years in duration, however the total budget amount will not exceed a one-time amount of $600,000 (direct plus indirect costs) per award. The project and budget periods of these awards will be the same. Any application received that exceeds the amount stated previously will not be considered responsive and will be returned to the applicant without being reviewed. The number of agreements funded will depend on the availability of Federal funds to support the projects and on the quality of the applications received. There is no