This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to fipronil as they enter food-baited boxes.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, telephone: (770) 488–8600; facsimile: (770) 488–8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within fifteen days of this notice will be considered.

Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: May 15, 2002.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–12649 Filed 5–20–02; 8:45 am]

BILLING CODE 4163–18–P

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 (DFSR), is announcing the availability of grant funds for the support of an innovative food safety program. Approximately $350,000 will be available in fiscal year 2002. FDA anticipates making at least seven awards, not to exceed $50,000 (direct and indirect costs combined) per award per year. 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. These grants are not intended to fund or conduct food inspections.

DATES: Submit applications by July 22, 2002.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Cynthia M. Polit, Grants Management Office (HFA–520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7180, e-mail: cpolit@oc.fda.gov. Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857. Application forms PHS–5161–1 (7/00) are available via the Internet at http://www.psc.gov/forms (revised 7/00).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (see **ADDRESSES**).

Regarding the programmatic aspects of this notice: Paul M. Raynes, or Anne Hope Scott, Division of Federal-State Relations, Office of Regulatory Affairs (HFC–150), Food and Drug Administration, 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, e-mail: dfsr@ora.fda.gov, on the Internet at http://www.fda.gov/ora/fed_state/default.htm.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA will support projects covered by this notice under title XVII of the Public Health Service Act (42 U.S.C. 1702). 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, local, and tribal governments.

FDA urges applicants to submit work plans that address specific objectives of ''Healthy People 2010.'' Applicants may obtain a hard copy of the ''Healthy People 2010'' objectives, volumes I and II, Conference Edition (B0074), for $22 per set, by writing to the Office of Disease Prevention and Health promotion (ODPHP) Communication Support Center, P.O. Box 37366, Washington, DC 20013–7366. Each of the 28 chapters of ''Healthy People 2010'' is priced at $2 per copy. Telephone orders can be placed to the center on 301–468–5690. The center also sells the complete Conference Edition in CD–ROM format (B0071) for $5. This publication is available as well on the Internet at http://www.health.gov/healthypeople/. Internet viewers should proceed to ''Publications.''

The Public Health Service 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 FDA mission to protect and advance the physical and mental health of the American people.

II. Background

ORA is the inspection component of the FDA and has some 1,100 investigators and inspectors who cover the country's approximately 95,000 FDA-regulated businesses. These investigators inspect more that 15,000 facilities a year. In addition to the standard inspection program, they conduct special investigations, conduct food inspection recall audits, perform consumer complaint inspections, and collect samples of regulated product. FDA has relied on the States in assisting with the these activities through formal contracts, partnership agreements, and other informal arrangements. Under the Food Safety Initiative (FSI), the demands on both the agency and the States has increased. Procedures need to be reviewed and innovative changes made that will increase effectiveness and efficiency and conserve resources. ORA will support FSI by: (1) Effectively and efficiently ensuring compliance of regulatory products; and (2) providing high quality, science-based work that results in maximizing consumer protection.

Under FSI, FDA is mandated to develop innovative food safety programs that would be utilized nationally by State and local food safety regulatory agencies. Even though the American food supply is among the safest in the world, millions of Americans are stricken by illness each year caused by the food they consume, and some 7,000 Americans a year, primarily the very young and elderly, die as a result. The goal of FSI is to further reduce the incidence of foodborne disease to the greatest extent possible. Innovative food safety programs that are developed at the State and local levels and have national implication could enhance programs that are developed at the Federal level.

A. Project Goals, Definitions, and Examples

The specific objective of this program will be to complement, develop, or improve State and local food safety programs that would have applicability to food safety programs nationwide. Examples of food safety projects are retail food (food manufacturers,

processors, wholesalers, and warehouses); egg safety program; milk safety program; shellfish safety program. Applications that address one of the food safety projects and fulfill the following specific project objectives will be considered for funding.

Each application must address only one project. Applicants may apply for more than one project area, but must submit a separate application for each project. These grants are not to fund or conduct food inspections for food safety regulatory agencies. Applications relating to the Retail Food Program area should be applicable to program improvement processes for FDA's draft ''Recommended National Retail Food Regulatory Program Standards'' (http://vm.cfsan.fda.gov/~dms/ret-toc.html) (see review criteria).

There are two key project areas identified for this effort:

1. Inspection

Development of innovative regulatory inspection methods or techniques for the inspection process of various food establishments in order to improve effectiveness and efficiency. Innovative Regulatory Program Methodology projects must demonstrate an effect on factors that contribute to foodborne illness in all, or a segment of, food industry programs. For example, projects could address key elements from the draft entitled ''Recommended National Retail Food Regulatory Program Standards,'' such as the five Food Code Interventions (management knowledge, employee health, hands as a vehicle of contamination, time/temperature relationships, and consumer advisory), or the five Centers for Disease Control and Prevention risk factors (improper holding temperature, inadequate cooking, contaminated equipment, unsafe source, and poor personal hygiene). Other examples of projects in this area could include prevention and control of *Listeria monocytogenes* in retail and foodservice environments and projects that address shell egg safety, such as refrigeration, safe handling, or labeling. The goal of these projects should be to achieve efficient and effective compliance with regulations that affect factors that contribute to foodborne illness.

2. Education and Health Information Dissemination

Development of innovative education projects and materials for State and local food safety regulatory officials that foster consistency and uniform application of State and local food regulations. These education projects and/or materials must be reproducible by other State and local food safety regulatory agencies. These projects may incorporate concurrent education of both State and local food safety regulatory agencies and the food industry.

B. Applicability

All grant application projects that are developed at State, local, and tribal levels must have national implication or application that can enhance Federal, State, and local food regulatory programs and are likely to reduce factors that cause foodborne illness. At the discretion of FDA, successful project formats will be made available to interested Federal, State, local, and tribal food safety regulatory agencies. No grant will be awarded for projects that do not support the FDA Food Code.

III. Reporting Requirements

Semiannual progress reports as well as a final program progress report and a final financial status report (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer within 90 days of the expiration date of the grant. The final program progress report must provide full written documentation of the project, copies of any results, as described in the grant application, and an analysis and evaluation of the results of the project. The documentation must be in a form and contain sufficient detail such that other State and local food safety regulatory agencies could reproduce the final project.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least semiannually by the project officer. Project monitoring may also be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be duly recorded in the official file and may be available to the recipient upon request.

IV. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of a grant. These grants will be subject to all policies and requirements that govern the project grant programs of FDA, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 also apply to this program and are implemented through Department of Health and Human Services regulations at 45 CFR part 100. Executive Order 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOCs is included in the application kit. The SPOC should send any State review process recommendations to FDA's administrative contact (see **ADDRESSES**). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60 day cut-off.

B. Eligibility

This grant program is only available to State, local, and tribal government food regulatory agencies. (See SPOC requirements stated previously.)

C. Length of Support

The length of support will be for 1 year from date of award.

V. Review Procedure and Criteria

All applications submitted in response to this request for application (RFA) will first be reviewed by grants management and program staff for responsiveness. Responsiveness is defined as submission of a complete application with original signatures on or before the required submission date as listed previously in this document. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration. An application will be considered nonresponsive if any of the following criteria are not met: (1) If it is received after the specified receipt date; (2) if the total dollar amount requested from FDA exceeds $50,000; (3) if all required original signatures are not on the face, assurance, or certification pages of the application; (4) if there is no original signature copy; (5) if it is illegible; (6) if the material presented is insufficient to permit an adequate review; (7) if the application demonstrates an inadequate understanding of the intent of the RFA; (8) if the application is determined to be essentially similar to projects that have been funded in the past; or (9) if for any reason the results of the project, including computer software, cannot be made available to other State, local, and tribal food regulatory agencies. All applicants are encouraged to check the

list of projects that received funding in prior years under this program on the Internet at www.fda.gov/ora/fed_state/Innovative_Grants.html.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Other award criteria will include availability of funds and overall program balance in terms of geography. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their application. All questions of a technical or programmatic nature must be directed to ORA's program staff (see **ADDRESSES**) and all questions of an administrative or financial nature must be directed to the grants management staff (address above).

Applications will be given an overall score and judged based on all of the following criteria:

1. Application budgets must remain within the $50,000 cap for combined direct and indirect costs. Applications exceeding this dollar amount will be returned as nonresponsive.

2. Applications must provide in detail, a sound rationale and appropriate grant design to address the objectives of the RFA.

3. The project must be generic enough in nature to be used by other State, local, and tribal food regulatory agencies.

4. Applications must include a detailed explanation of the desired goals and outcomes of the project.

5. Only for applications relating to the Retail Food Program, the outcomes of the project should be applicable to program improvement process for FDA's draft ''Recommended National Retail Food Regulatory Program Standards.'' These standards will serve as a guide to the regulatory retail food program. The standards apply to the operation, management, and promotion of a regulatory retail food program focused on the reduction of risk factors known and suspected to cause foodborne illness. The FDA draft ''Recommended National Retail Food Regulatory Program Standards'' are found on the Internet at http://vm.cfsan.fda.gov/~dms/ret-toc.html or contact your local FDA Regional Retail Food Specialist from the list provided in the application packet.

6. Applications must include a full description of the project design, a detailed implementation plan, methods of execution, and timeline for completion. The application must include a detailed description of measures of effectiveness and a description of the source documents or data collection methods for establishing the baseline for measurement.

7. Applications must address the adequacy of facilities, expertise of project staff, equipment, databases and support services needed for the project.

8. Applicants and applicants' subgrantees and subcontractors must ensure compliance that any projects developed in whole or in part with Federal funds may be made available to other State, local, and tribal food regulatory agencies by FDA or its agents. Such copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

VI. Submission Requirements

The original and two copies of the completed Grant Application Form PHS–5161–1 (Revised 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Cynthia M. Polit (see **ADDRESSES**). The application receipt date is July 22, 2002. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. No supplemental or addendum material will be accepted after the receipt date.

The outside of the mailing package and item 2 of the application face page should be labeled ''Response to RFA–FDA–ORA–02–Project I (Inspection) or ''RFA–FDA–ORA–02–Project II (Education and Health Information Dissemination).'' Submit only one project application (an original and two copies) per package.

VII. Method of Application

A. Submission Instructions

Each application must be submitted under separate cover. Do not submit more than one application (original with two copies) per envelope. Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

Do not send applications to the Center for Scientific Research, National Institutes of Health (NIH). Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant. Instructions for completing the application are included in Form PHS–5161–1. FDA is unable to receive applications via Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 5161–1 (Rev 7/00). All instructions for the enclosed Standard Form 424 (SF–424) should be followed using the nonconstruction application pages. A properly formatted sample application for the grant can be accessed on the Internet at http://www.fda.gov/ora/fed_state/Innovative_Grants.html. Applications may be considered nonresponsive if not submitted in the proper order.

The face page of the application should indicate ''RFA–FDA–ORA–02–Project I (Inspection),'' or ''RFA–FDA–ORA–02–Project II (Education and Health Information and Dissemination).'' Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161–1 were approved and issued under Office of Management and Budget Circular A–102.

C. Legend

Unless disclosure is required by FOIA as amended (5 U.S.C. 552), as determined by the freedom of information officials of Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number and paragraph by the applicant as

containing restricted or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: May 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12665 Filed 5–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1360]

Guidance for Industry on Preparation of Food Contact Notifications: Administrative; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Preparation of Food Contact Notifications: Administrative.'' This guidance document is intended to provide guidance for industry regarding the preparation of food contact notifications (FCNs). FDA is providing this guidance as part of its implementation of the premarket notification process for food contact substances (FCSs) established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments concerning this guidance document at any time.

ADDRESSES: Submit written comments concerning this guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http//www.fda.gov/dockets/ecomments. Submit written requests for single copies of the guidance document to the Office of Food Additive Safety (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your requests. You also may request a copy of the guidance document by electronic mail at OPAPMN@CFSAN.FDA.GOV, or by telephone to the Office of Food Additive Safety at 202–418–3087 (voice) or FAX 202–418–3131. All requests should be identified with the guidance document by its title. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Public Law 105–115) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish an FCN process as the primary method for authorizing new uses of food additives that are FCSs. A ''food contact substance'' is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' FDA expects most new uses of FCSs that previously would have been regulated by issuance of a listing regulation in response to a food additive petition or would have been exempted from the requirement of a regulation under the ''Threshold of Regulation'' process will be the subject of FCNs. FDA is announcing the availability of the guidance document entitled ''Preparation of Food Contact Notifications: Administrative.'' This guidance document is intended to provide guidance for industry regarding the preparation of FCNs. FDA is providing this guidance document as part of its implementation of the premarket notification process for FCSs established by FDAMA.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the data and information that should be submitted in an FCN and the plan for administration of the FCN program. This guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. This guidance document is a level 1 guidance under the agency's good guidance practices (GGPs) regulations (21 CFR 10.115).

Because it is a level 1 guidance under the agency's GGPs, FDA announced the availability for comment of a draft of the guidance document ''Preparation of Food Contact Notifications: Administrative'' in a notice published in the **Federal Register** of July 13, 2000 (65 FR 43377). The comment period for the guidance document closed on September 26, 2000. FDA received no comments on the guidance document. However, FDA did receive three comments on the proposed rule published simultaneously with the July 13, 2000, notice of availability. Portions of these three comments are relevant to the guidance document and FDA has addressed the relevant portions of the comments in the guidance document announced by this notice. Thus, in accordance with its GGPs, FDA now is reissuing this guidance document in final form.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at http://www.cfsan.fda.gov/~dms/guidance.html.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written and electronic comments regarding the guidance document at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the guidance.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12663 Filed 5–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0199]

Advertisements for High-Intensity Mercury Vapor Discharge Lamps; Revocation of Compliance Policy Guide 7133.13

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled ''Sec. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13)''