application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (OMB control number 0910–0001 approved by OMB until March 31, 2005). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well established, low risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. The burden totals do not include an increase in burden. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					4,000

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

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8818 Filed 5–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0065]

Risk Assessment of the Public Health Impact From Foodborne Listeria Monocytogenes in Smoked Finfish; and Evaluation of Food Code Provisions That Address Preventive Controls for Listeria Monocytogenes in Retail and Foodservice Establishments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 5, 2005, the comment period for the notice that appeared in the **Federal Register** of March 4, 2005 (70 FR 10650). In the notice, FDA requested comments and scientific data and information to assist the agency in its plans to conduct a risk assessment for *Listeria monocytogenes* in smoked finfish and to evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments and scientific data and information.

DATES: Submit written and electronic comments and scientific data and information by July 5, 2005.

ADDRESSES: Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS–06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1903.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 2005 (70 FR 10650), FDA published a notice with a 60-day comment period to request comments and scientific data and information to assist the agency in its plans to conduct a risk assessment for *L. monocytogenes* in smoked finfish (smoked finfish risk assessment) and to evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments.

For the smoked finfish risk assessment, the agency specifically requested information on the following topics:

1. *L. monocytogenes* levels in raw fish, smoked fish, and finished product,
2. Effect of mitigation measures (e.g., ozonation, acidified sodium chlorite) to reduce *L. monocytogenes* levels in raw and finished product,
3. Potential for transfer of *L. monocytogenes* to food from contaminated food contact and noncontact surfaces during manufacturing and/or processing (e.g., equipment, workers, floor drains, etc.),
4. Potential for transfer of *L. monocytogenes* from the slicer to cold-smoked fish,
5. Impact of adding inhibitors (e.g., bacteriocins and bacteriocins-producing bacterial strains or sodium lactate) to smoked finfish to reduce or prevent *L. monocytogenes* growth,
6. Impact of frozen versus refrigerated storage conditions on levels of *L. monocytogenes*,
7. Impact of time and temperature on levels of *L. monocytogenes* for commercial and home storage conditions of finished product, and
8. Effect of training regarding sanitation and hygienic practices on reducing the levels of *L. monocytogenes* in smoked finfish.

For evaluating the Food Code provisions for preventive controls for *L. monocytogenes* in retail and foodservice establishments, the agency specifically requested the following data and information:

1. *L. monocytogenes* levels in products stored in retail and foodservice establishments,
2. Levels of environmental contamination and harborage of *L. monocytogenes* on food contact and nonfood contact surfaces in retail and foodservice establishments (e.g., equipment, workers, floor drains, etc.),

3. Effects of short- and long-term refrigerated storage on levels of *L. monocytogenes* in retail and foodservice establishments,

4. Impact of time and temperature on levels of *L. monocytogenes* in products stored in retail and foodservice establishments,

5. Efficacy of cleaning procedures and sanitizing agents on environmental surfaces and utensils,

6. Frequency of use and impact of adding inhibitors to food products in retail and foodservice establishments to reduce or prevent *L. monocytogenes* growth, and

7. Effect of training regarding hygienic practices and sanitation on levels of *L. monocytogenes* in products in retail and foodservice establishments.

Interested persons were given until May 3, 2005, to submit comments and scientific data and information.

The agency has received a request for a 60-day extension of the comment period for the notice. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful response to the notice.

FDA has considered the request and is extending the comment period for the notice for an additional 60 days, until July 5, 2005. However, the agency does not anticipate granting any further extensions of the comment period.

II. Request for Comments and for Scientific Data and Information

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments, scientific data, and information on this document. Submit a single copy of electronic comments, scientific data, and information or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8838 Filed 4–29–05; 11:30 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Funding Opportunity Title: Food Safety Task Force Conference Announcement Type: New Request for Applications Funding Opportunity Number: RFA–FDA–ORA–2005–3 Catalog of Federal Domestic Assistance (CFDA) Number(s):93–103

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a revised request for application (RFA) that will replace the announcements published June 25, 2004 (69 FR 35651) and February 4, 2005 (70 FR 6015). FDA, in collaboration with the Centers for Disease Control and Prevention (CDC), is announcing the availability of conference grant funding for meetings of State Food Safety and Food Security Task Forces. The original announcement of availability of funding for State Food Safety Task Force Meetings, published in the **Federal Register** on January 24, 2000 (65 FR 3720), is superseded by this announcement. This revised announcement provides new policies that apply to the State Food Safety and Food Security Task Force Meetings Conference Grant Program. The FDA views this program as an ongoing program announcement, contingent on the availability of funds.

DATES: The application receipt date is July 5, 2005.

ADDRESSES: Applicants are strongly encouraged to apply electronically by visiting the Web site at *http://www.grants.gov* and following instructions under ''APPLY.'' Applications also are available from, and completed applications may be submitted to, Michelle Caraffa, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7025, e-mail: *mcaraffa@oc.fda.gov*. Application forms PHS 5161–1 are available via the internet at: *http://www.psc.gov/forms* (Revised 7/00). Applications hand carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–500), rm. 2129, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Michelle N. Caraffa (see **ADDRESSES**).

Regarding the programmatic issues of this notice: Stephen Toigo, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs (ORA), Food and Drug Administration (HFA–150), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–2906, E-mail: *stoigo@ora.fda.gov*, or access the Internet at *http://www.fda.gov/ora/fed__state/default.htm*.

For general ORA program information: Contact your Regional Food Specialists at *http://www.fda.gov/ora/fed__state/DFSR__Activities/food* specialists.htm.

SUPPLEMENTARY INFORMATION: The purpose of the Food Safety and Food Security Task Force meetings is to foster communication and cooperation within the States among State and local food safety regulatory agencies. The meetings should: (1) Provide a forum for all the stakeholders of the food safety system—regulatory agencies, academia, industry, consumers, State legislators, and other interested parties; (2) assist in adopting or implementing the Food Code; and (3) promote the integration of an efficient statewide food safety system that maximizes the protection of the public health through early detection and containment of foodborne illness. Each Task Force shall develop its own guidelines for work, consensus decision-making, size and format, at its initial meeting. FDA DFSR will provide meeting guidelines and organization documents as requested.

I. Funding Opportunity Description

FDA is issuing a revised RFA which will replace the announcements published June 25, 2004 (69 FR 35651) and February 4, 2005 (70 FR 6015). FDA, in collaboration with the CDC, is announcing the availability of conference grant funding for meetings of State Food Safety and Food Security Task Forces. The original announcement of availability of funding for State Food Safety Task Force Meetings, published in the **Federal Register** on January 24, 2000, is superseded by this announcement. This revised announcement provides new policies that apply to the State Food Safety and Food Security Task Force Meetings Conference Grant Program. The FDA views this program as an ongoing program announcement, contingent on the availability of funds.

FDA and CDC view State based Food Safety and Food Security Task Forces as important mechanisms for promoting food safety, food security program coordination, and information