FDA in determining its infrastructure needs, as well as the process for evaluating third-party certification programs. The criteria for selection for that pilot are based upon the attributes set forth in the draft guidance.

As with the pilot, the 12 attributes discussed in the draft guidance are intended to provide a model that could be tailored for particular categories of products and incorporated by FDA as it recognizes third-party certification programs for those products. These attributes incorporate such things as the authority of the certification body to adequately inspect the establishments seeking certification, qualifications, and training for the third-party inspectors, self-assessment of the certification programs and its inspectors, elements of an effective inspection program, notification to FDA, and preventing conflicts of interest. While FDA invites comments on all aspects of the draft guidance, FDA is particularly interested in receiving comments on this list of attributes for the certification program. More specifically, we would like to know whether there are some attributes that should be removed or added and whether the draft guidance provides sufficient information about each attribute. We are also interested in knowing how this list compares with existing, well-accepted guidelines or requirements for certification programs.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on Voluntary Third-Party Certification Programs for Foods and Feeds. It 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 statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/oc/guidance/thirdpartycert.html* or *http://www.regulations.gov*.

Dated: July 7, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15715 Filed 7–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0382]

Voluntary Third-Party Certification Programs for Imported Aquacultured Shrimp; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking third-party certification bodies that certify foreign processors of aquacultured shrimp for compliance with FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) regulations to volunteer to participate in a pilot program to be conducted by FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA). The goal of the pilot program is to gather technical and operational information that will assist FDA in determining its infrastructure needs, as well as the process for evaluating third-party certification programs, in order to assist FDA in moving towards broader recognition of voluntary third-party certification programs, including third-party certification programs for aquacultured shrimp, at a later time.

DATES: Submit written and electronic requests to participate in the pilot program by August 25, 2008.

ADDRESSES: Submit written requests to participate in the pilot program to the Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Submit electronic requests to participate to *aquaculture@fda.hhs.gov*. We strongly encourage interested persons to electronically submit their request to participate.

FOR FURTHER INFORMATION CONTACT: Brett Koonse, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1700.

SUPPLEMENTARY INFORMATION:

I. Background

Ensuring the safety of food for human and animal use is a shared responsibility between the public and private sectors. FDA has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but it is primarily the responsibility of industry to ensure that foods products intended for human and animal consumption in the United States are safe and meet applicable FDA standards. An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requesting, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as quality) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. requirements.

On July 18, 2007, the President issued Executive Order 13439 to establish the Interagency Working Group on Import Safety (Working Group). On November 6, 2007, the Working Group released an ''Action Plan for Import Safety: A Roadmap for Continual Improvement'' (Action Plan) (*http://www.importsafety.gov/report/actionplan.pdf*). The Action Plan contains 14 broad recommendations and 50 specific short- and long-term action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. The Action Plan stresses the importance of the private sector's responsibility for the safety of its products and the importance of ongoing private-sector mechanisms and experience as a basis for ongoing, substantive public-private collaboration. The public and private sectors have a shared interest in import safety, and substantive improvement will require

the careful collaboration of the entire importing community.

Recommendation 2 of the Action Plan is to ''verify compliance of foreign producers with United States safety and security standards through certification.'' Third-party certification can augment the Federal Government's and the importing community's ability to help ensure that products imported into the United States meet U.S. safety and security standards. The Action Plan states ''[f]or foreign producers, the ability to participate in voluntary certification programs could allow products from firms that comply with U.S. safety and security standards to enter the United States more quickly. This would facilitate trade, while allowing federal departments and agencies to focus their resources on products from non-certified firms or for which information suggests there may be safety or security concerns. This would allow federal departments and agencies to more effectively target their resources.''

Action Steps 2.2 and 2.4 of the Action Plan call for the recognition or development of voluntary third-party certification programs, based on risk, for foreign producers of certain products who export to the United States and the creation of incentives for foreign firms to participate in voluntary certification programs and for importers to purchase only from certified firms.

In conjunction with the Action Plan, on November 6, 2007, FDA released its Food Protection Plan (FPP), a comprehensive strategy designed to bolster efforts to better protect the Nation's food supply (*http://www.fda.gov/oc/initiatives/advance/food/plan.html*). The FPP is a three-part plan that uses science and a risk-based approach of prevention, intervention and response to ensure the safety of domestic as well as imported foods eaten by American consumers. The FPP emphasizes certification as a way to help verify the safety of products from a growing food establishment inventory, both foreign and domestic.

On April 2, 2008, FDA published a notice in the **Federal Register** (73 FR 17989) requesting comments by May 19, 2008, on the use of third-party certification programs for foods and animal feeds. The notice was FDA's first step in soliciting public input in the design and development or recognition of voluntary third-party certification programs.

In order to assist FDA in moving towards broader recognition of third-party certification programs, FDA is now seeking voluntary participants for a third-party certification pilot program for aquacultured shrimp. This pilot program is the next step in gathering technical and operational information that will assist FDA in determining its infrastructure needs. The information from this pilot also will assist with subsequent steps, such as developing the process for evaluating third-party certification programs should FDA decide to recognize voluntary third-party certification programs and to consider certification in its decision making. Certification might be considered, for example, in decision making regarding determination of establishment inspection priorities, entry admissibly, field exam and sampling priorities, ''may proceed'' rates, and requests by firms to have their products removed from an import alert. If FDA were to recognize third-party certification programs, we would do so on a product-by-product basis. We would also provide an opportunity for both foreign and domestic certification bodies to voluntarily seek FDA recognition and for foreign and domestic establishments to voluntarily seek certification.

II. Voluntary Third-Party Certification Pilot Program

A. Scope and Selection Attributes

FDA is seeking a limited number of third-party certification bodies (such as private, non-government entities, other Federal government, State government, and foreign government agencies) that currently certify foreign processors of aquacultured shrimp for compliance with FDA's Seafood HACCP regulations to volunteer to participate in the pilot program. Participants in the pilot program will be asked to provide FDA with technical feedback on the pilot.

A limited number of voluntary participants are needed for the pilot program. The agency will use its discretion in choosing participants for Phase II of the pilot (see following discussion) from those who apply during Phase I of the pilot based on the following attributes:

1. Authority of the Certification Body. The certification body should have the authority to perform inspection activities, collect and evaluate records, collect and analyze samples, and assess and report on compliance as necessary to ensure certification standards and requirements are met and maintained.

2. Qualification and Training for Inspectors. The certification body should ensure that its inspectors are adequately trained to perform their work assignments. Such training includes course work, field work, and continuing education.

3. Elements of an Effective Inspection Program. The certification body should ensure that its inspectors are consistently using established, widely-recognized standards when performing inspections. The inspector should prioritize and target the elements of producing, manufacturing, processing, packing, and holding that pose the greatest risk to human and/or animal health. The certification body should have written policies and procedures describing the protocol to be used by all inspectors during an inspection. During an inspection, inspectors should verify that the establishments and products meet and maintain certification criteria that include the following:

- The processor is in compliance with applicable FDA regulatory requirements for food, including FDA's Seafood HACCP regulations;
- If appropriate, the processor has in place, and effectively executes, management systems that ensure the safety of all shrimp products, from production to distribution, as applicable, including the feed used, the hatchery, the growing area, harvesting, processing, and transportation. This may include a preventive control program for farms (e.g., Good Aquaculture Practices, Best Management Practices, farmer training along with farm inspections), a verification program (e.g., an effective testing scheme to ensure products are free of unapproved drugs, chemicals, and pathogens), a traceability program, or recall and follow-up procedures in case of an outbreak or illness associated with a product.

4. Inspection Audit Program. The third-party certification body should conduct audits of its inspections to assess the effectiveness of the inspections and sample collections and to ensure the competency and consistency of its inspectors.

5. Cooperation with FDA and Other Appropriate Government Officials When Safety Problems Occur. The certification body should cooperate as necessary with FDA and other appropriate government authorities if the certification body discovers a situation in which there is a reasonable probability that U.S. consumers may consume or be exposed to a food product that could cause serious adverse health consequences or death to humans or animals, whether the contamination or problem was caused intentionally or unintentionally. Such cooperation may include notification to relevant agencies inside and outside of the United States, where the food is sold or distributed. Moreover, when FDA has reliable information from the Centers for

Disease Control and Prevention (CDC) or other reliable sources about a health risk associated with an FDA-regulated food product and FDA is conducting a traceback of a product, FDA may request information from the certification body regarding the supply chain. Such information may be requested based on preliminary information that an establishment under the certification program may be implicated. The certification body should provide FDA with this information in a timely manner. Such information would be disclosed (or protected from disclosure) in accordance with applicable laws and policies.

6. Compliance and Corrective Action. The certification body should have strategies, procedures, and actions to ensure the establishments and products it certifies comply with FDA laws and regulations and otherwise meet certification standards, to take action when there is non-compliance, and to evaluate the effectiveness of corrective action programs.

7. Industry Relations. At a minimum, the certification body should provide establishments seeking certification with information about current FDA requirements and guidances.

8. Resources. The certification body should have sufficient resources, such as technological tools and infrastructure, to carry out its certification program.

9. Self-Assessment of Overall Certification Program. In addition to auditing the inspection program, the certification body should assess the effectiveness of the certification program as a whole.

10. Laboratories. The certification body should have access to laboratory services to support the program functions. The laboratories should be accredited by an accreditation body operating in accordance with International Organization for Standardization (ISO) standard 120/IEC 17011, General requirements for Accreditation bodies accrediting conformity assessment bodies.

11. Notifications to FDA. The certification body should promptly notify FDA of problems or changes that can affect product safety or security. We expect prompt notification of the following:

a. Safety Issues. The certification body should immediately notify FDA if an inspector finds or discovers a situation in which there is a reasonable probability that U.S. consumers may consume or be exposed to a food that could cause serious adverse health consequences or death to humans or animals. This information may pertain to intentional or unintentional contamination. The certification body should provide detailed information that describes the extent and nature of the problem and allows us to identify the product and source, including traceability records.

b. Fraud. The certification body should promptly notify FDA if it has information that the establishment or any of its officers or employees engages in any fraudulent acts related to foods, including providing false information to the certification body or any inspectors acting on its behalf.

c. Criminal Acts. The certification body should promptly notify FDA if it has information that the establishment or any of its officers or employees has been convicted of a crime relating to foods or any crime involving false statements, fraud, or dishonesty.

12. Conflict of Interest. The certification body and its inspectors should be free from conflicts of interest.

These attributes are described in greater detail in a draft guidance issued today entitled, ''Voluntary Third Party Certification Programs for Foods and Feeds'' (*http://www.fda.gov/oc/guidance/thirdpartycert.html* or *http://www.regulations.gov*). The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Certification bodies interested in participating in this pilot should review the draft guidance.

Favorable consideration will be given to third-party certification bodies that: (1) Currently certify foreign shrimp processors for controls designed to ensure the safety of the product from production through distribution, in addition to compliance with FDA's Seafood HACCP regulations; (2) certify processors of aquacultured shrimp in countries that export significant amounts of aquacultured shrimp to the United States; and/or (3) are accredited or are in the process of becoming accredited by a recognized accreditation body.

B. Pilot Program and FDA Audit

The pilot program will be conducted in two phases. Phase I begins with the issuance of this document and will run through December 2008. During Phase I, FDA will receive and evaluate requests to participate in the pilot, including conducting paper audits to determine whether applicants have the attributes described in this document. During the paper audit, applicants will be asked to provide FDA with a list of inspectors for the products covered under this pilot and the inspectors' locations. In addition, applicants may be asked to provide FDA with other documents such as certification or recertification audit reports and product sampling results.

Phase II will begin in December 2008 with notification of the applicants that have been selected for participation. During Phase II, which will run through June 2009, FDA will conduct onsite audits of third-party certification programs by accompanying certain inspectors during certification and/or recertification inspections. FDA will also conduct targeted sampling of imported shrimp products. FDA may elect to increase the ''may proceed'' rate during Phase II for shrimp products from certified establishments, if warranted based on information generated as a result of participation in the pilot. FDA's decision would be made on a case-by-case basis.

The pilot program will not preclude FDA, U.S. Customs and Border Protection, or other agencies from inspecting or taking other action with respect to any firm or imported product. Further, FDA may terminate a certifying body's participation in the pilot at any time for any reason.

C. Duration

FDA plans to conduct the pilot program for a period of 12 months, beginning in July 2008. Either phase of the pilot program may be extended or shortened as appropriate.

D. Submission of Requests to Participate

Written requests to participate in the pilot program should be submitted to the Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Electronic requests to participate should be submitted to *aquaculture@fda.hhs.gov*. We strongly encourage interested persons to electronically submit their request to participate. Written and electronic requests to participate in the pilot program should be submitted to FDA by August 25, 2008.

The request to participate should include the following information:

1. The docket number found in brackets in the heading of this document;

2. The applicant's name, telephone number, address, and e-mail address;

3. A signed statement indicating the following:

a. The certification body, its inspectors, and any subcontractors that might be used (e.g., laboratories, sampling services) agree to participate in the pilot program and are free from any conflict of interest;

b. The certification body agrees to undergo an FDA audit of its certification program, and supply information requested by FDA for the evaluation of the participant's certification program or of products certified under the program; and

c. The certification body agrees to: (i) Immediately notify FDA if an inspector finds or discovers a situation in which there is a reasonable probability that U.S. consumers may consume or be exposed to a food that could cause serious adverse health consequences or death to humans or animals; (ii) promptly notify FDA if it has information that the establishment or any of its officers or employees engages in any fraudulent acts related to foods, including providing false information to the certification body or any inspectors acting on its behalf; and (iii) promptly notify FDA if it has information that the establishment or any of its officers or employees has been convicted of a crime relating to foods or any crime involving false statements, fraud, or dishonesty.

4. The name and address of each certified foreign aquaculture shrimp farming and/or processing facility that has agreed to participate in the pilot and to be available for an FDA audit and a description of the products certified;

5. A detailed written description of the extent to which the applicant's certification program conforms to the 12 attributes listed previously; and

6. Any accreditation the applicant may have from an accreditation body operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011, General requirements for accreditation bodies accrediting conformity assessment bodies, or information confirming that the applicant is in the process of becoming accredited by such an accreditation body.

FDA notes that statements made to FDA as part of this pilot are subject to the provisions of 18 U.S.C. 1001, which provides for criminal penalties for anyone who, among other things, makes a materially false, fictitious, or fraudulent statement to the U.S. government.

E. Evaluation of Pilot Program

FDA intends to evaluate the pilot program based on several factors, including, but not limited to, the extent to which certification provides adequate assurances of the safety of aquacultured shrimp from certified establishments, FDA's ability to accurately and efficiently evaluate third-party certification programs, and FDA's current ability and future needs to operationalize the recognition of third-party certification programs and the utilization of certification in agency decision making. After FDA evaluates the pilot program, the agency may extend, modify, or terminate the pilot program.

As noted previously, FDA will take the results of the pilot program into consideration in future decisions of whether to provide incentives for voluntary certification, including considering whether to adjust the ''may proceed'' rate for imports, and/or begin the process to recognize voluntary third-party certification programs for aquacultured shrimp or other food or feed on a non-pilot basis.

Dated: July 7, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15713 Filed 7–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Nursing, Office of Public Health Nursing

Funding Opportunity Number: HHS–2008–IHS–PHN–0001.

Announcement Type: New.

Catalog of Federal Domestic Assistance Number(s): 93.933.

Key Dates:

Application Deadline Date: August 4, 2008.

Review Date: August 15, 2008.

Award Announcement: August 22, 2008.

Earliest Anticipated Start Date: August 29, 2008.

I. Funding Opportunity Description

The Indian Health Service (IHS) Division of Nursing, Office of Public Health Nursing (PHN) announces a new competitive grant application for community based model of PHN case management services. This program is authorized under the Snyder Act, 25 U.S.C. 13; Section 301(a), Public Health Service Act, as amended; and the Indian Health Care Improvement Act (IHCIA) 25 U.S.C. 1652. This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA).

The purpose of the program is to improve health outcomes of high risk patients through a community case management model that utilizes the PHN as case manager. Research indicates nursing case management is a cost effective way to maximize health outcomes. The PHN Model of community based case management utilizes roles and functions of PHN services of assessment, planning, coordinating services, communication and monitoring. The goals and outcomes of the PHN Case Management model are early detection, diagnosis, treatment and evaluation that will improve health outcomes in a cost effective manner. This model utilizes all prevention components of primary, secondary and tertiary prevention in the home with patient and family. The community based case management model addresses the scope of practice of PHN working with individuals and families in a population-based practice.

Health disparities are greater for American Indian/Alaska Native (AI/AN) communities than the general United States population. Infant mortality is greater in the AI/AN population than United States in general, suicide rates are greater, unintentional injuries are greater, and chronic disease is increasing. This project will focus on a PHN community based case management model. The project will be conducted in a phased approach, using the nursing process—assessment, planning, implementation, and evaluation.

First Phase: Assessment—Conduct a comprehensive community assessment. The Senior Nurse Consultant will recommend a community assessment tool and provide appropriate training to the grantees in the Fall of 2008. Include, if available, pertinent data from the various community assessments and local health status data of the community in the community assessment.

In addition, obtain input from key stake-holders such as, community members and healthcare administration and community health groups to determine the health care priorities. Develop plans for project sustainability.

The PHN case management model will develop case management services addressing the priority health issues identified from the community assessment. The PHN case management program will establish policies and procedures, best practice (BP) for services, and mechanisms for tracking outcomes using the recommended PHN community based case management tool to improve the health care status.

Second Phase: Planning—After the community assessment is completed and priorities for Public Health Nursing case management services are determined, planning the case management model project will begin. Obtain additional staff training needed