a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan. The guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility as well as the broader Plan to comprise one Plan for each manufacturer. Based on FDA's data on the number of manufacturers that would be covered by the guidance, we estimate that approximately 70 manufacturers will develop a Plan as recommended by the guidance (i.e., 1 Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours to develop, maintain, and update.

The guidance also encourages manufacturers to include a procedure in their Plan for notifying the Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately two manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

The guidance also refers to previously approved collections of information found in FDA regulations. Under the guidance, if a manufacturer obtains information after releasing an MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately at *drugshortages@fda.hhs.gov* in adherence to existing recall reporting regulations (21 CFR 7.40; OMB control number 0910–0249), or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

In addition, the following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190–0139. The guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (see, e.g., § 211.180) that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The guidance states that a Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Absenteeism guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA of Plan Activation and Deactivation	2	1	2	16	32

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Absenteeism guidance	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop Initial Plan	70	1	70	500	35,000

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

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14812 Filed 6–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement To Support the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single-source application for the award of a cooperative agreement in fiscal year 2013 (FY13) to the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station Poultry Unit located in Salisbury, NC. Egg-associated illness due to *Salmonella* is a major public health concern, with table eggs being the primary source of *Salmonella* Enteritidis. Therefore, an FDA priority is to implement preventative measures to reduce the vertical and horizontal transmission of *Salmonella* Enteritidis and other *Salmonella* serovars to table eggs and poultry products. The goal of

this collaborative project between FDA and the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station is to utilize a commercial research facility to parallel the transmission (vertical and horizontal) of *Salmonella* found within the egg-production industry and how alterations in physical feed characteristics and housing may influence vertical and horizontal transmission. Additionally, this study aims to examine how commercially utilized disinfection protocols affect horizontal transmission of *Salmonella* in alternative versus traditionally housed layer hens. Moreover, this study may reveal other serovars of *Salmonella* present within the commercial egg industry which may pose a potential health risk to consumers. While historically the concern over *Salmonella* has focused on *Salmonella* Enteritidis, there is a potential concern that other *Salmonella* serovars could be a source for egg-transmitted human salmonellosis. Hence, this study aims to investigate the occurrence, transmission, and virulence of varying *Salmonella* serovars.

DATES: Important dates are as follows:

1. The application due date is July 15, 2013.

2. The anticipated start date is September 2013.

3. The expiration date is July 16, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov*. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Scientific/Programmatic Contact: Ondulla Toomer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 8301 Muirkirk Rd., MOD–1 (HFS–025), Laurel, MD 20708, 240–402–3430, email: *ondulla.toomer@fda.hhs.gov*.

Grants Management Contact: Kimberly Pendleton Chew, Office of Acquisitions and Grant Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2105 (HFA 500), Rockville, MD 20857, 301–827–9363, email: *kimberly.pendleton@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *www.fda.gov/food/newsevents/default.htm*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–031 93.103

A. Background

Egg-associated illness due to *Salmonella* is a major public health concern, with table eggs being the primary source of *Salmonella* Enteritidis. Infected individuals may suffer gastrointestinal distress, short-term or chronic arthritis, or even death.

Salmonella Enteritidis is transmitted vertically (due to bacterial infection of the reproductive organs infecting the yolk, albumen, and/or membranes) or horizontally (due to microbial contamination post-oviposition from environmental or cloacal contamination). Upon the horizontal transmission of *Salmonella,* the micro-organism penetrates the eggshell infecting the yolk, albumen, and egg membranes. Therefore, an FDA priority is to implement preventative measures to reduce the vertical and horizontal transmission of *Salmonella* Enteritidis and potentially other *Salmonella* serovars to table eggs and poultry products (tissues). Intensive genetic selection for enhanced egg production has altered the ability to resist microbial contamination within laying hen breeders. Thus, it is imperative that interventional strategies be studied to ensure the safety of egg and poultry products for consumption.

Various studies (Bjerrum et al., 2005; Huang et al., 2006, Santos, 2006) have demonstrated that increasing the grain particle size in the diet reduced the vertical transmission of *Salmonella.* Bjerrum et al. (2005) reported that broilers fed a finely ground pelleted corn diet had a higher *Salmonella* population in the gizzard than broilers fed a coarsely ground corn pelleted diet. In parallel, Huang et al. (2006) reported a higher incidence of *Salmonella Typhimurium* in the gizzard and cecal contents of broilers fed a finely ground corn pelleted diet, suggesting that feed structure may influence *Salmonella* colonization by altering the gastrointestinal microenvironment.

B. Research Objectives

Research objectives include utilizing a commercial research facility to parallel the transmission (vertical and horizontal) of *Salmonella* found within the egg production industry; indicating how alterations in physical feed characteristics and housing (traditional caging versus free-range) may influence vertical and horizontal transmission; and examining how commercially utilized disinfection protocols affect horizontal transmission of *Salmonella* in free-range versus traditionally housed layer hens. All research and microbiological analysis will be conducted at facilities housed at North Carolina State University, Prestage Department of Poultry Science and Piedmont Research Station, Salisbury, NC, using North Carolina State University Institutional Animal Care and Use Committee (IACUC) approved protocol #11–024–A. This cooperative agreement will provide support for collaborative research conducted between FDA–CFSAN–OARSA-Immunobiology and North Carolina State University, Prestage Department of Poultry Science utilizing the commercial research facility Piedmont Research Station to meet the following projected milestones:

1. Assess the routes of *Salmonella* transmission to eggs, egg and poultry products (tissues), and examine tissue colonization.

2. Assess the immunological responses of the layer hen to *Salmonella* challenge post- and pre-molting.

3. Examine the prevalence of differing *Salmonella* serovars in various environmental layer hen housing systems (conventional cage, enriched cage systems, and free-range).

4. Examine the effect of various nutritional intervention strategies (physical feed characteristics, antimicrobials, immuno-enhancing feed ingredients) on vertical transmission rates in a commercial-style environment.

5. Examine the use of differing disinfection protocols on the rates of horizontal transmission in various environmental layer hen housing systems (conventional cage, enriched cage systems, and free-range).

C. Eligibility Information

Competition is limited to the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station because FDA finds that the North Carolina State University Department of Poultry Science and the Piedmont Research Station are uniquely qualified to fulfill the objectives outlined in the proposed cooperative agreement.

The goal of this collaborative project is to utilize a commercial research facility to parallel the transmission (vertical and horizontal) of *Salmonella* found within the egg production industry and how alterations in physical feed characteristics and housing may influence vertical and horizontal transmission.

The Piedmont Research Station Poultry Unit is a unique facility that has housing for over 15,000 commercial layers, 8,000 broiler breeders, and incubation capacity to hatch more than 52,000 eggs at one time utilizing both

multistage and single-stage incubation. The Prestage Department of Poultry Science Research and Teaching Units in Raleigh, NC conduct research at the Piedmont Research Station. Research at both unit locations includes commercial layers, commercial broiler breeders, broilers, and commercial-style incubation. Piedmont Research Station routinely conducts the Layer Performance Management Test in North America, with studies in applied production practices and nutrition management. These facilities are able to evaluate the effects of a research project on a size and scale that mimics commercial poultry operations.

The North Carolina State University feed mill is a research and educational feed mill that is designed and equipped to manufacture a variety of feed mix characteristics, formulations, and feed forms. It is currently used by FDA for training purposes associated with the safe feed-safe food program, and is among the few research feed mills in the country that is associated with animal research facilities. The mill has all of the typical process equipment found in commercial feed mills, including an 8 ton/hr CPM hammer mill, 8 ton/hr RMS roller mill, micro bin-batching system, a 500 lb horizontal ribbon mixer, a 2 ton double-shaft ribbon mixer, a 1 ton/hr CPM pellet mill with counter-flow cooler, a 10 ton/hr Bliss pellet mill with counter-flow cooler, pellet screener, bagger, bulk ingredient bins, finished feed bins, and an automated computer-controlled batch mixing and process operation. This feed mill is able to manufacture feed of various feed ingredient grind size in mash or pellet forms.

While other academic institutions also have outstanding poultry and egg research programs, they do not have commercial style research facilities, feed mill, and resources to conduct large-scale commercial size research projects. Moreover, the North Carolina State University, Prestage Department of Poultry Science and Piedmont Research Facility are within close geographic proximity for collaboration with FDA's Department of Immunobiology. This will allow FDA's investigational scientists to travel by automobile on key experimental dates to initiate research experiments and to collect tissue and environmental samples. These samples will be transported within 24 hours back to FDA's Department of Immunobiology for microbiological testing and analysis.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition (CFSAN) intends to fund one award up to $50,000 total costs (direct plus indirect costs) for FY 2013. Future year amounts will depend on annual appropriations and successful performance.

B. Length of Support

The award will provide 1 year of support and include future recommended support for 4 additional years, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *www.fda.gov/food/newsevents/default.htm*. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp*. Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp*. After you have followed these steps, submit electronic applications to: *http://www.grants.gov*.

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14824 Filed 6–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels and Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through December 2013.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by July 22, 2013, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by July 22, 2013.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be sent electronically to *CV@OC.FDA.GOV,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., WO32 Rm. 5129, Silver Spring Maryland 20993–0002, or by fax to 301–847–8640. Information about becoming a member of an FDA advisory committee can be obtained by