Enteritidis (SE) prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))), to ensure that the agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–1070. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance. Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 9, 2009 (74 FR 33030), FDA issued the final rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. The final rule became effective September 8, 2009.

FDA is issuing the draft guidance as a level 1 draft guidance consistent with FDA’s good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on how to comply with certain measures designed to prevent SE from contaminating eggs on the farm, as well as how to sample for SE and maintain records documenting compliance with the final rule. 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910–0660.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Dated: August 9, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Intent To Award Patient Protection and Affordable Care Act Funding to Approved But Unfunded Applications (ABU) Formerly Received in Response to the American Recovery and Reinvestment Act of 2009 (ARRA) Centers for Disease Control and Prevention Funding Opportunity DP09–912ARRA09, “Communities Putting Prevention to Work” (CPPW)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides notice of CDC’s intent to fund additional Approved but Unfunded (ABU) cooperative agreement applications previously received and competed in response to CDC Funding Opportunity, CDC–ARPA–DP09–912ARRA09, “Communities Putting Prevention to Work” (CPPW). It is the intent of CDC to fund additional previously received applications with Patient Protection Affordable Care Act (PPACA), Section 4002, appropriations. To this end, CDC will remove the following ARRA–Specific Requirements published in the aforementioned funding opportunity announcement:

—Catalogue of Domestic Assistance Number 93.724
—Recovery Act-Specific Reporting Requirements

Recipients of Federal awards from funds authorized under Division A of the Recovery Act must comply with all requirements specified in Division A of the Recovery Act (Pub. L. 111–5), including reporting requirements outlined in Section 1512 of the Act and designated Recovery Act outcome and output measures as detailed at the end of this section. For purposes of reporting, Recovery Act recipients must report on Recovery Act sub-recipient (sub-grantee and sub-contractor) activities as specified below.

Not later than 10 days after the end of each calendar quarter, starting with the quarter ending __________, and reporting by __________, the recipient must submit quarterly reports to HHS that will posted to Recovery.gov, containing the following information:

a. The total amount of Recovery Act funds under this award;

b. The amount of Recovery Act funds received under this award that were obligated and expended to projects or activities;

c. The amount of unobligated award balances;

d. A detailed list of all projects or activities for which Recovery Act funds under this award were obligated and expended, including:
   • The name of the project or activity;
   • A description of the project or activity;
   • An evaluation of the completion status of the project or activity;
   • An estimate of the number of jobs created and the number of jobs retained by the project or activity (see OMB Guidance M–09–21, June 22, 2009) and;
   • For infrastructure investments made by State and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment under this Act, and the name of the person to contact at the agency if there
are concerns with the infrastructure investment.

e. Detailed information on any sub-
awards (sub-contracts or sub-grants) made by the grant recipient to include
the data elements required to comply with the Federal Funding
Accountability and Transparency Act of

For any sub-award equal to or larger
than $25,000, the following information:
- The name of the entity receiving the
sub-award;
- The amount of the sub-award;
- The transaction type;
- The North American Industry
Classification System code or Catalog of
Federal Domestic Assistance (CFDA)
number;
- Program source;
- An award title descriptive of the
purpose of each funding action;
- The location of the entity receiving
the award;
- The primary location of
performances under the award, including
the city, state, congressional district,
and county.
- A unique identifier of the entity
receiving the award and of the parent
entity of the recipient, should the entity
be owned by another entity;
- The date the sub-award was issued;
- The term of the sub-award (start/
end dates);
- The scope/activities of the sub-
award;
- The amount of the total sub-award
that has been obligated or disbursed by
the sub-recipient; and
- The amount of the total sub-award
that remains unobligated by the sub-
recipient.

f. All sub-awards less than $25,000 or
to individuals may be reported in the
aggregate, as prescribed by HHS.

g. Recipients must account for each
Recovery Act award and sub-award
(sub-grant and sub-contract) separately.
Recipients will draw down Recovery
Act funds on an award-specific basis.
Pooling of Recovery Act award funds
with other funds for drawdown or other
purposes is not permitted.

h. Recipients must account for each
Recovery Act award separately by
referencing the assigned CFDA number
for each award.

The definition of terms and data
elements, as well as any specific
instructions for reporting, including
required formats, will be provided in
subsequent guidance issued by HHS.

Buy American—Use of American Iron,
Steel, and Manufactured Goods

Recipients may not use any funds
obligated under this award for the
construction, alteration, maintenance, or
repair of a public building or public
work unless all of the iron, steel, and
manufactured goods used in the project
are produced in the United States unless
HHS waives the application of this
provision. (Recovery Act Sec. 1605)

Wage Rate Requirements

This term and condition shall not
apply to tribal contracts funded with this
appropriation. (Recovery Act Title
VII—Interior, Environment, and Related
Ages, Department of Health and
Human Services, Indian Health
Facilities) Subject to further
clarification issued by the Office of
Management and Budget, and
notwithstanding any other provision of
law and in a manner consistent with
other provisions of Recovery Act, all
laborers and mechanics employed by
contractors and subcontractors on
projects funded directly by or assisted
in whole or in part by and through the
Federal Government pursuant to this
award shall be paid wages at rates not
less than those prevailing on projects of
a character similar in the locality as
determined by the Secretary of Labor in
accordance with subchapter IV of
chapter 31 of title 40, United States
Code. With respect to the labor
standards specified in this section, the
Secretary of Labor shall have the
authority and functions set forth in
Reorganization Plan Numbered 14 of
1950 (64 Stat. 1267; 5 U.S.C. App.) and
section 3145 of title 40, United States
Code. (Recovery Act Sec. 1606)

Preference for Quick Start Activities
(Recovery Act)

In using funds for this award for
infrastructure investment, recipients
shall give preference to activities that
can be started and completed
expeditiously, including a goal of using
at least 50 percent of the funds for
activities that can be initiated not later
than 120 days after the date of the
enactment of Recovery Act. Recipients
shall also use grant funds in a manner
that maximizes job creation and
economic benefit. (Recovery Act Sec.
1602)

Limit on Funds (Recovery Act)

None of the funds appropriated or
otherwise made available in Recovery
Act may be used by any State or local
government, or any private entity, for
any casino or other gambling
establishment, aquarium, zoo, golf
course, or swimming pool. (Recovery
Act Sec. 1604)

Disclosure of Fraud or Misconduct

Each recipient or sub-recipient
awarded funds made available under
the Recovery Act shall promptly refer to
the HHS Office of Inspector General any
credible evidence that a principal,
employee, agent, contractor, sub-
recipient, subcontractor, or other person
has submitted a false claim under the
False Claims Act or has committed a
criminal or civil violation of laws
pertaining to fraud, conflict of interest,
brbery, gratuity, or similar misconduct
involving those funds. The HHS Office
of Inspector General can be reached at
http://www.oig.hhs.gov/fraud/hotline/

Recovery Act: One-Time Funding

Unless otherwise specified, Recovery
Act funding to existent or new awardees
should be considered one-time funding.

Schedule of Expenditures of Federal
Awards

Recipients agree to separately identify
the expenditures for each grant award
funded under Recovery Act on the
Schedule of Expenditures of Federal
Awards (SEFA) and the Data Collection
Form (SF–SAC) required by Office of
Management and Budget Circular A–
133, “Audits of States, Local
Governments, and Non-Profit
Organizations.” This identification on
the SEFA and SF–SAC shall include the
Federal award number, the Catalog of
Federal Domestic Assistance (CFDA)
number, and amount such that separate
accountability and disclosure is
provided for Recovery Act funds by
Federal award number consistent with
the recipient reports required by
Recovery Act Section 1512(c). (2 CFR
215.26, 45 CFR 74.26, and 45 CFR
92.26)

Responsibilities for Informing Sub-
Recipients

Recipients agree to separately identify
to each sub-recipient, and document at
the time of sub-award and at the time of
disbursement of funds, the Federal
award number, any special CFDA
number assigned for Recovery Act
purposes, and amount of Recovery Act
funds. (2 CFR 215.26, 45 CFR 74.26, and
45 CFR 92.26)

Reporting Jobs Creation

HHS’ recipients of Recovery Act
funding who are subject to Section 1512
reporting should report job-created data
as prescribed in Section 5 of the Office
of Management and Budget (OMB)
guidance M–09–21. HHS will not accept
statistical sampling methods to estimate
the number of jobs created and retained.
All recipients must report a direct and
comprehensive count of jobs, as
specified by OMB guidance M–09–21.
See Section 5.3 of the OMB guidance for
more information on calculating jobs,
including job estimation examples. For the full OMB guidance, please visit: http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09–21.pdf.

Conclusion of Recovery Act–Specific Reporting Requirements

Recipient Reporting Requirements under PPACA

The removal of ARRA Section 1512 Reporting Requirements does not absolve the applicant from reporting project status as well as the other terms and conditions set forth in the above-referenced CPPW FOA and the Notice of Cooperative Agreement Award. Recipients funded with PPACA appropriations will be required to report project status on a semi-annual basis. Specific reporting requirements will be detailed in the Terms and Conditions of the Notice of Cooperative Agreement Award.

CFDA Number 93.520 is the PPACA-specific CFDA number for this initiative. It will replace CFDA Number 93.724 published in the above-referenced CPPW Funding Opportunity Announcement (FOA).

Award Information:
Approximate Current Fiscal Year Funding: $34,000,000.
Approximate Number of Awards: 11.
Approximate Average Award: $3,000,000.

Fiscal Year Funds: Patient Protection and Affordable Health Care Act of 2010.
Anticipated Award Date: 30 Sep 2010.
Budget Period: 24 months.
Project Period: 24 months.

Application Selection Process: CDC will apply the same selection methodology published in the CPPW FOA, CDC–RFA–DP09–912ARRA09. Applications will be funded in order by score and rank determined by the previously held review panel.

In addition, as was referenced in the CPPW FOA, funding decisions may be made to ensure:
• Representation of tobacco and obesity/physical activity/nutrition across communities, including a varied type of interventions and evidence-based strategies.
• Geographical distribution of The Communities Putting Prevention to Work Initiative nationwide.
• Inclusion of communities of varying sizes, including rural, suburban, and urban communities.
• Inclusion of populations disproportionately affected by chronic disease and associated risk factors.

CDC will provide justification for any decision to fund out of rank order.

CDC will add the following Authority to that which is reflected in the published Funding Opportunity:

—Section 4002 of the Patient Protection and Affordability Care Act (Public Law 111–148.)

DATES: The effective date for this action is August 12, 2010 and remains in effect until the expiration of the project period of the PPACA funded applications.

FOR FURTHER INFORMATION CONTACT:
Elmira Benson, Deputy Director, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341. telephone: (770) 488–2802, e-mail: EBBenson@cdc.gov

SUPPLEMENTARY INFORMATION: On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (PPACA). PPACA is designed to improve and expand the scope of health care coverage for Americans. Cost savings through disease prevention is an important element of this legislation and PPACA has established a Prevention and Public Health Fund (PPHF) for this purpose. Specifically, the legislation states in Section 4002 that the PPHF is to “provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs”. PPACA and the Prevention and Public Health Fund make improving public health a priority with investments to improve public health.

The PPHF states that the Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Services Act, for prevention, wellness and public health activities including prevention research and health screenings, such as the Community Transformation Grant Program, the Education and Outreach Campaign for Preventative Benefits, and Immunization Programs.

Both ARRA and PPACA legislation affords an important opportunity to advance public health across the lifespan and to reduce health disparities by supporting an intensive community approach to chronic disease prevention and control. Therefore, awarding cooperative agreements with PPACA funds under PPHF to ABUs to carry out CPPW objectives is consistent with the purpose of PPHF, as stated above, to provide for the expanded and sustained national investment in prevention and public health programs. Further, the Secretary allocated funds to CDC, pursuant to the PPHF, for the types of activities that the CPPW initiative is designed to carry out.

Therefore, the CPPW program activities CDC proposes to fund with PPACA appropriations are authorized by the amendment to the Public Health Services Act which authorized the Prevention and Wellness Program as embodied in CDC RFA DP09–912ARRA09.

Tanja Popovic,
Deputy Associate Director for Science, Centers for Disease Control and Prevention.
[FR Doc. 2010–19907 Filed 8–11–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Epi R01s, Data Analysis R21s, and K99 Applications.

Date: August 23, 2010.
Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: SAMUEL RAWLINGS, PhD, Chief, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301–451–2020, rawlings@nei.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, Clinical Trials.

Date: August 24–25, 2010.
Time: 8 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NEI Division of Extramural Research, 5635 Fishers Lane, Bethesda, MD 20892, (Virtual Meeting).