ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Form name | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| Invasive Methicillin-resistant Staphylococcus aureus ABCs Case Report Form. | State Health Department. | 10 | 609 | 20/60 | 2030 |
| ABCs Invasive Pneumococcal Disease in Children Case Report Form. | State Health Department. | 10 | 41 | 10/60 | 68 |
| Neonatal Group B Streptococcal Disease Prevention Tracking Form. | State Health Department. | 10 | 37 | 20/60 | 123 |
| Total | | | | | 4918 |

Dated: May 23, 2008.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E8–12192 Filed 5–30–08; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Public Health Service Act (PHS); Delegation of Authority

Notice is hereby given that I have delegated to the Director, National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), and the Director, Division of Global Migration and Quarantine (DGMQ), NCPDCID, with authority to redelegate, the authorities vested in the Director, Centers for Disease Control and Prevention, under sections 361(a), (b), (c), (d), and 362, Title III, of the PHS Act (Control of Communicable Diseases, 42 U.S.C. 264 and 265. The authority delegated under 361(a) does not include the authority to promulgate regulations.

This delegation became effective upon date of signature. In addition, I have affirmed and ratified any actions taken by the Director, NCPDCID, the Director, DGMQ, NCPDCID, or their subordinates which involved the exercise of authorities delegated herein prior to the effective date of the delegation.

Dated: May 20, 2008.

**Julie Louise Gerberding,**

*Director, Centers for Disease Control and Prevention.*

[FR Doc. E8–12176 Filed 5–30–08; 8:45 am]

**BILLING CODE 4160–18–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Committee on Immunization Practices (ACIP)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

*Times and Dates:* 8 a.m.–6 p.m., June 25, 2008. 8 a.m.–5 p.m., June 26, 2008.

*Place:* CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent ''Oz'' Nelson Auditorium, Atlanta, Georgia 30333.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

*Matters to be Discussed:* The agenda will include discussions on Rotavirus Vaccines; Combination Vaccines; MMRV Vaccine; Human Papillomavirus Vaccines; Pneumococcal Vaccines; Measles Outbreaks in the United States (2008); Adult Immunization Schedule; Anthrax Vaccine; Influenza Vaccines; Rabies Vaccine and Biologicals; Vaccine Supply; and Immunization Safety Update. There may be VFC voting on the Rotavirus, Combination and Human Papillomavirus Vaccines.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Antonette Hill, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., (E–05), Atlanta, Georgia 30333, Telephone (404) 639–8836, Fax (404) 639–8905.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and ATSDR.

Dated: May 27, 2008.

**Elaine Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E8–12234 Filed 5–30–08; 8:45 am]

**BILLING CODE 4160–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Food Safety Research; Investigations Focused on Promoting the Safety of Produce

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA-Center for Food Safety and Applied Nutrition (CFSAN)) is announcing the availability of approximately $1.0 million in research funds for fiscal year (FY) 2008. It is anticipated that individual grants will receive a total of $250,000 to $500,000 to cover both direct and indirect costs. These funds will be used to support research efforts to advance the safe transportation and preparation of produce and to help reduce the incidence of foodborne illness that may be associated with fresh produce consumption. The award will provide 18 months of support. There will be no additional years of noncompetitive continuation support. A copy of the full text of this announcement will be posted in Grants.gov and on FDA's Center for Food Safety and Applied Nutrition Web site at *http://www.cfsan.fda.gov/list.html*.

Key Dates: Receipt Date: Applications are due within 90 days after the publication of the funding opportunity in the **Federal Register**.

## I. Funding Opportunity Description

The Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) maintains an active intramural research program. This research is focused on five primary CFSAN program priorities; ensuring the safety of food, dietary, supplements and cosmetics; improving nutrition; and promoting the security and integrity of the food supply. When resources permit, CFSAN supports extramural research grants intended to help advance these program priorities. The extramural program endeavors to support novel research efforts, expertise, and resources not found within CFSAN. In particular, it is intended that any additional extramural research efforts in food safety will complement the Center's intramural research efforts, and generally enhance the Agency's and the Nation's ability to reduce the incidence of food borne illness and protect the integrity of the nation's food supply.

Applications submitted in response to this Request for Application must be submitted electronically through Grants.gov (*http://www.grants.gov*) using the SF 424 Research and Related (R&R forms and the SF 424 (R&R) Application Guide.) Paper applications will not be accepted.

*Project Emphasis*

FDA is announcing the availability of competitively awarded funding for FY 2008 to be used for research intended to help enhance produce safety. Proposed projects designed to fulfill the specific objectives of either of the following requested project topic categories will be considered for funding. Applications may address only one project and its objectives per application. It should be noted that CFSAN will place greater value on those proposals addressing the objectives in a manner that will lead to practical solutions, which, if implemented, will help improve the safety of prepared and consumed fresh-cut produce. No proposed projects should involve human research subjects.

*A. Project Topic Category 1*

Conduct laboratory based studies assessing the handling of fresh-cut produce by consumers that may compromise the microbiological safety of the product prior to its consumption. Quantifiable information is being sought regarding the consequences of typical consumer handling behaviors that compromise fresh produce safety and about practical alterations in consumer behaviors that may be easily employed to improve the safety of the product they eat. These must be laboratory based studies and not consumer behavioral studies involving human subjects.

*B. Project Topic Category 2*

Identify and assess problem(s) that occur during the transportation of fresh produce between producer processing facilities and point of retail sale to the consumer. The research may focus on an individual problem and its impact on a single commodity or a group of commodities. Alternatively, the research may focus on a set of related or interdependent problems and their impact on a single commodity or a group of commodities. It is expected the research effort will provide practical solutions that can be used to enhance product safety and integrity during the transportation phase of its production.

## II. Award Information

*Mechanism of Support*

This Request for Application will use the Research Project Grant R01 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project. FDA will support the competitively awarded grants under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241).

*Announcement Type: New Competing Research Grant (R01)*

*Request for Applications (RFA) Number: RFA-FD-08-005*

*Catalog of Federal Domestic Assistance Number: 93.103*

## III. Eligibility Information

*A. Eligible Applicants*

The grants are available to any foreign or domestic, public or private, for-profit or nonprofit entity (including State and local units of government). Federal agencies that are not part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations that engage in lobbying activities, as described in section 501(c) (4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

*B. Cost Sharing or Matching*

Cost sharing is not required.

*C. Other-Special Eligibility Criteria*

Applicants may submit more than one application, provided each application is scientifically distinct.

## IV. Application and Submission

*A. Request Application Information*

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this funding opportunity through the Grants.gov Apply *http://www.grants.gov* Web site. Only the forms package directly attached to this specific funding opportunity in Grants.gov can be used.

Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.

Direct questions regarding Grants.gov registration should be directed to Grants.gov Customer Support at 800–518–4726 or e-mail *support@grants.gov*.

1. Dun and Bradstreet Number (DUNS)

Applicants are now required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9–digit identification number that uniquely identifies business entities. To obtain a DUNS number, call Dun and Bradstreet at 1–866–705–5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet. For foreign entities the Web site is *https://eupdate.DNB.com*.

2. Central Contractor Registration

Applicants must register with the CCR database. You must have a DUNS number to begin your registration. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for completing a registration is through the Web site at *http://www.ccr.gov*. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process. In order to access grants.gov an applicant will be required to register with the Credential Provider. Information about this is available at *http://www.grant.gov/CredentialProvider*.

*B. Content and Form of Application Submission*

The SF424 (R&R) has several components. Some components are required, others are optional. The forms package associated with this Request for Application in Grants.gov/APPLY includes all applicable components (required and optional). The package should be labeled ''Response to RFA-

FD–08–005.'' If you experience technical difficulties with your online submission you should contact Gladys Melendez-Bohler by telephone 301–827–7168 or by e-mail *gladys.melendez-bohler@fda.hhs.gov*.

Data and information included in the application will generally not be publicly available prior to the funding of the application. After funding has been awarded, data and information included in the application will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)) and FDA's implementing regulations (including 21 CFR Part 20 and §§ 20.61, 20.105, and 20.106). By accepting funding, the applicant agrees to allow FDA to publish specific information about the grant. Collecting information on Form SF424 (R&R) has been approved and assigned OMB control number 4040–0001.

*C. Submission Dates and Times*

The application submission receipt date is within 90 days after the date of the publication of the Funding Opportunity Announcement in the **Federal Register**. The application will be accepted electronically until the established receipt date.

On time submission requires that applications be successfully submitted to Grants.gov no later than 5 p.m local time (of the applicant's institution/organization).

*D. Intergovernmental Review*

The regulations issued under Executive Order 12372, Intergovernmental Review of Federal Program (45 CFR Part 100) do not apply.

*E. Funding Restrictions*

This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including Provisions of 42 CFR Part 52 and 45 CFR Parts 74 and 92. All grants are subject to the terms and conditions, cost principles, and other considerations described in the January 6, 2007, HHS Grants Policy Statement that are applicable based on your recipient type and the purpose of this award. This includes any requirements in Parts I and II (available at *http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*).

Although consistent with the HHS Grants Policy Statement (GPS), any applicable statutory or regulatory requirements, including 45 CFR parts 74 or 92, directly apply to this award apart from any coverage in the HHS GPS.

**V. Agency Contacts**

For issues regarding the programmatic aspects of this notice: Mark Wirtz, Center for Food Safety and Applied Nutrition (HFS–002), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2001, e-mail: *mark.wirtz@fda.hhs.gov*. For issues regarding the administrative and financial management aspects of this notice contact, Gladys Melendez-Bohler at 301–827–7168 or by e-mail at *gladys.melendez-Bohler@fda.hhs.gov*.

Dated: May 23, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–12159 Filed 5–30–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2007–D–0364] (formerly Docket No. 2007D–0080)**

### Guidance for Industry on Indexing Structured Product Labeling; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Indexing Structured Product Labeling.'' This guidance explains that the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will index structured product labeling (SPL) in the product labeling for human drug and biologic products. This guidance also makes recommendations to industry on how to submit input regarding the indexing information in the SPL.

**DATES:** Submit written or electronic comments on agency guidance documents at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring MD 20993–0003, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance can also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Laurie Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20993–0002, *laurie.burke@fda.hhs.gov*, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled ''Indexing Structured Product Labeling.'' This guidance explains that CBER and CDER will index SPL in the product labeling for human drug and biological products. This guidance also makes recommendations to industry on how to submit input regarding the indexing information in the SPL.

A Health Level Seven (HL7) standard, SPL enables the electronic exchange of the content of labeling and other regulated product information using the extensible markup language. The SPL standard enables the inclusion of indexing elements with product labeling. These machine readable identifiers enable users with clinical decision support tools and electronic prescribing systems to rapidly search and sort product information found in product labeling. Indexing the content of labeling with SPL will greatly facilitate the efficient communication of important drug information to the public, helping create a more robust nationwide system for promoting the safe and effective use of drugs.

After completing a 6-month pilot project evaluating how best to add indexing elements, FDA determined that the most efficient strategy is for FDA, not individual applicants, to index the SPL using a phased approach. We will index the pharmacological class during the first phase. We are adding