ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Residents, first responders, business owners, employees, customers.	General Survey	800	1	30/60
	Rapid Response Registry Form	50	1	7/60
Residents	Household Survey	110	1	15/60
Hospital staff	Hospital Survey	40	1	30/60
Staff from state, local, or tribal health agencies.	Medical Chart Abstraction Form	250	1	30/60
	Veterinary Chart Abstraction Form	30	1	20/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–22691 Filed 9–23–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Performance Review Board Members

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members who are reviewing performance for Fiscal Year 2014.

FOR FURTHER INFORMATION CONTACT: Sharon O'Brien, Deputy Director, Executive and Scientific Resources Office, Human Capital and Resources Management Office, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Mailstop K–15, Atlanta, Georgia 30341, Telephone (770) 488–1781.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons will serve on the CDC Performance Review Boards or Panels, which will oversee the evaluation of performance appraisals of Senior Executive Service members for the Fiscal Year 2014 review period:

Christine Branche, Co-Chair
James Seligman, Co-Chair
Barbara Bowman
Janet Collins
Hazel Dean
Jane Gentleman
Joseph Henderson
Jeffrey Napier
Jennifer Parker
Tom Sinks
Kalwant Smagh
James Stephens

Dated: September 19, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014–22714 Filed 9–23–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1287]

Announcement of Requirements and Registration for the 2014 Food and Drug Administration Food Safety Challenge

Authority: 15 U.S.C. 3719.

AGENCY: Food and Drug Administration, HHS.

Award Approving Official: Erik Mettler, Deputy Associate Commissioner, Food and Drug Administration/Office of Foods and Veterinary Medicine.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the 2014 FDA Food Safety Challenge, a prize competition under the America COMPETES Reauthorization Act of 2010. The 2014 FDA Food Safety Challenge is an effort to advance breakthroughs in foodborne pathogen detection, specifically with the goal of accelerating the detection of *Salmonella* in fresh produce. As FDA's food safety program incorporates preventive control measures through the implementation of the FDA Food Safety Modernization Act, quicker detection of these harmful bacteria will help to prevent foodborne illnesses.

DATES:

1. Phase I submission period: September 23 to November 9, 2014.
2. Phase II judging of submissions and selection of finalists: November 10, 2014, to January 6, 2015.
3. Phase III field accelerator, inclusive of finalist mentorship, boot camp, and demo day: January 8 to March 5, 2015.
4. Phase IV final judging: March 5 to March 11, 2015.
5. Winner(s) announced: March 12, 2015.

FOR FURTHER INFORMATION CONTACT: Chad P. Nelson, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4643.

SUPPLEMENTARY INFORMATION:

I. Background

While the American food supply is among the safest in the world, the Centers for Disease Control and Prevention (CDC) estimates that 1 in 6 Americans is sickened by foodborne illness annually, resulting in about 3,000 deaths each year. It is estimated that the overall negative economic impact of foodborne illness in the United States, including medical costs, quality-of-life losses, lost productivity, and lost-life expectancy, may be as high as $77 billion per year. *Salmonella* represents the leading cause of deaths and of hospitalizations related to foodborne illness. Contaminated produce is responsible for nearly half of foodborne illnesses and almost a quarter of foodborne-related deaths.

The 2014 FDA Food Safety Challenge is a call to scientists, academics, entrepreneurs, and innovators from all disciplines to submit concepts applying novel and/or advanced methodologies to foster revolutionary improvements in foodborne pathogen detection.

Specifically, concepts should apply cutting-edge techniques to achieve significant improvements in the speed of the FDA's detection methods for *Salmonella* with identification to the subtype/serovar level in minimally processed fresh produce. FDA is most interested in concepts that explore the acceleration or elimination of sample preparation and/or enrichment in the testing process, and/or those that employ novel or revolutionary techniques to achieve pathogen detection. Concepts may combine new techniques with existing methodologies, such as polymerase chain reaction, and must describe where time savings are achieved in the testing process as well as the expected time from unprepared food sample to verifiable result.

The statutory authority for this challenge competition is section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

II. Subject of the Challenge Competition

The primary goal of the challenge is to advance breakthroughs in foodborne pathogen detection, specifically to significantly accelerate detection of *Salmonella* in produce, in order to support FDA's effort to ensure the safety of America's food supply.

The secondary goals of the challenge are:

- To bring new innovators to FDA's foodborne pathogen testing processes;
- To increase public awareness about food safety, foodborne pathogen testing, and FDA's role in those areas; and
- To promote open government and citizen participation to improve innovation in the Federal Government.

This challenge is designed to solicit breakthrough solutions from advanced scientific and research areas, such as, but not limited to metagenomics (or other next-generation sequencing methods), spectroscopy, application of nanotubes/nanotechnology, quantum detection methods, and electrical detection methods. Although concepts must specifically be able to address the detection of *Salmonella,* with identification to the subtype/serovar level, in minimally processed fresh produce, the ability of the solution to address testing for other microbial pathogens and in other foods or complex matrices is encouraged. Submissions must describe how the technique would increase speed of pathogen detection efforts (starting from an unprepared food sample, through verification of pathogen(s)) without sacrificing specificity and sensitivity or comparability reference methods. FDA is most interested in methods that would accelerate or eliminate sample preparation and/or enrichment in the testing process. Submitted concepts can be targeted at any point in the food system (i.e. harvest, packaging, distribution, point of sale, etc.), however concepts should specify which point(s) they are targeting and how the technique would be implemented. Though submissions may be theoretical in terms of application to food safety, all entries must be able to demonstrate a path to practical development of their concept and a plan to move to proof of concept over the course of the challenge. Submissions should include relevant data with reference to use of the concept/technique, such as any initial verification results, any available proof of concept, or relevant data from the technique's use in adjacent industries. During the field accelerator phase, which will include a live boot camp, finalists will refine their submissions with the assistance of FDA food safety and pathogen testing experts. Feedback will focus on helping finalists to clarify their concepts and ensure they are in line with FDA's needs and capabilities, maximize impact on food safety, and can be reasonably executed. At the end of the field accelerator phase, finalists will present their refined concepts to the judges at a demo day and provide a final report describing how their submission was modified based on the feedback from FDA subject matter experts.

III. Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, an individual or entity:

- Must have entered a submission on *www.foodsafetychallenge.com* under the rules promulgated by FDA.
- Must have complied with all the requirements under this section.
- Must be (1) an individual or team of U.S. citizens or permanent residents of the United States each of whom are 18 years of age and over or (2) an entity incorporated in and maintaining a primary place of business in the United States. Foreign citizens can participate as employees of an entity that is properly incorporated in the United States and maintains a primary place of business in the United States.
- May not be a Federal entity or Federal employee acting within the scope of their employment. An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

Employees of FDA, the U.S. Department of Agriculture's Food Safety and Inspection Service, the CDC, Luminary Labs, LLC, each of their affiliates, and/or any other individual or entity associated with the development, evaluation, or administration of the challenge as well as members of such persons' immediate families (spouses, children, siblings, parents), and persons living in the same household as such persons, whether or not related, are not eligible to participate in the challenge.

Entrants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in a competition, whether the injury, death, damage, or loss arises through negligence or otherwise.

Entrants must also agree to indemnify the Federal Government against third-party claims for damages arising from or related to competition activities.

Entrants are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in the challenge.

By participating in the challenge, each entrant who works with pathogenic organisms such as *Salmonella* in support of its submission agrees to follow the requirements for Biosafety Level II laboratory operations, as outlined in the 5th edition of ''Biosafety in Microbiological and Biomedical Laboratories,'' available at *http://www.cdc.gov/biosafety/publications/bmbl5/.*

IV. Registration Process for Participants

To register for the 2014 FDA Food Safety Challenge, participants can access *http://foodsafetychallenge.com/* and click on Submission Form.

V. Amount of the Prize

The total prize pool for the 2014 FDA Food Safety Challenge is $500,000. From the $500,000 prize pool, up to 5 finalists will be awarded $20,000 each following the open submission phase and judging of submissions. After the field accelerator phase and final

judging, the winner(s) will receive the remainder of the prize money.

VI. Payment of the Prize

Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. FDA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

VII. Basis Upon Which Winner(s) Will Be Selected

A panel of expert judges will select up to five finalist teams from the pool of eligible entries. These finalists will then refine their concepts during the field accelerator phase and will present the concept at demo day. The judging will be based and scored upon the judges' own discretion as to the quality of each entry according to the following finalist evaluation criteria, with equal weighting (i.e., 20 percent for each).

A. Finalist Evaluation Criteria

- Speed: Proposed reduction in time from unprepared food sample to verified pathogen to subtype/serovar level for *Salmonella* in fresh, minimally processed produce. The ability of the solution to also address testing in other foods and other complex matrices is encouraged. The ability of the technique to also address additional pathogens such as Shiga toxin-producing *Escherichia coli* is encouraged.
- Improved detection and path to impact: Strength of evidence, data, and/or argumentation regarding the application of submission's technique to create impactful acceleration and improvement of foodborne pathogen detection, inclusive of improvements in specificity and sensitivity for *Salmonella* and possibly other pathogens.
- Applicability: Applicability of solution to FDA testing processes.
- Revolutionary: Whether the concept would be a revolutionary improvement over the FDA's current testing procedures with potential to make a major impact on food testing.
- Execution: Perceived ability of submitting team or individual to execute and develop their concept.

B. Winner Selection Criteria

Winner selection criteria will include finalist evaluation criteria plus the following criterion: Demonstration of team's/individual's ability to effectively iterate and improve their concept over the course of the field accelerator phase.

VIII. Additional Information

FDA reserves the right to suspend, postpone, terminate, or otherwise modify the challenge, or any entrant's participation in the challenge, at any time at FDA's discretion.

IX. Intellectual Property

Entrants retain ownership of their concepts, including any software, research, or other intellectual property that they develop in connection therewith, subject to the license granted to FDA to use publicly posted materials as set forth herein. By participating in the challenge, each entrant hereby irrevocably grants to FDA and Luminary Labs, LLC, a limited, non-exclusive, royalty free, worldwide license and right to reproduce, publicly perform, publicly display, and use the submission to the extent necessary to administer the challenge, and to publicly perform and publicly display the submission abstract, including, without limitation, for advertising and promotional purposes relating to the challenge.

Entrants retain all rights in the submission and any invention or work, including any software, submitted as part of the submission, subject to the following:

- A nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any such invention or work throughout the world, should the submission win; and
- A license in the submission or work submitted as part of the submission for the United States to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so, should the submission win.

Dated: September 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22682 Filed 9–23–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1601]

Custom Device Exemption; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Custom Device Exemption.'' FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the Food, Drug, and Cosmetic Act (the FD&C Act). The intent of this guidance is to define terms used in the custom device exemption, explain how to interpret the ''five units per year of a particular device type'' language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Custom Device Exemption'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Division of Premarket and Labeling Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–5770, *CustomDevices@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The custom device exemption is set forth at section 520(b) of the FD&C Act (21 U.S.C. 360j(b)). A custom device is in a narrow category of devices for which, because of the rarity of a patient's medical condition or a physician's special need, compliance