2014 FDA Food Safety Challenge

Rules, Terms & Conditions

Table of Contents

RULES, TERMS & CONDITIONS

CHALLENGE DESCRIPTION

The 2014 U.S. Food and Drug Administration (FDA) Food Safety Challenge (also referred to as the "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 FDA's** detection methods for ***Salmonella*** with identification to the subtype 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 (PCR), and must describe where time savings are achieved in the testing process as well as expected time from unprepared food sample to verifiable result.

These Official Rules, Terms & Conditions apply to the 2014 FDA Food Safety Challenge. Please read these Rules, Terms & Conditions carefully before submitting to the 2014 FDA Food Safety Challenge.

The Challenge will be conducted in four phases: 1) Challenge launch and open submissions; 2) Judging of submissions and selection of finalists; 3) Field Accelerator (inclusive of finalist mentorship, Boot Camp, and Demo Day); and 4) Final judging and selection of winner(s). Up to five finalist teams will be selected from the open submission pool based on the evaluation criteria listed below. The total prize pool is $500,000. Finalists will be awarded $20,000 each. Finalists are encouraged to use their winnings to improve upon their concepts through the course of the Challenge. Finalists will be included in a Field Accelerator phase, as described below.

FIELD ACCELERATOR DESCRIPTION

The Field Accelerator phase starts with the Finalist Announcement and runs through Demo Day, when finalists present their concepts to the judging panel. During this period, the finalist teams will iterate and improve upon their concepts in preparation for the Demo Day on March 5, 2015 (subject to change). Feedback will focus on helping teams to clarify their concepts, ensure they are in line with FDA's needs and capabilities, maximize impact on food safety, and can be reasonably executed.

GENERAL ELEMENTS OF THE FIELD ACCELERATOR PHASE

1. **Mentorship:** Finalist teams will have access to FDA subject matter experts ("SMEs") who will act as mentors throughout the Field Accelerator, helping the finalists to iterate and improve their concepts. Mentors will have a set number of hours available for phone counseling and will be available to speak to finalist on ways of improving their concepts. Example areas that mentors might help teams include: 1) Concept applicability to FDA testing process; 2) Comparability to FDA validation standards; and 3) General expertise in food safety and/or pathogen testing.
2. **Boot Camp:** The Boot Camp is required for finalists and is intended to be a live event, likely to be held in the Washington, D.C. metropolitan area. Finalists will receive guidance through teaching modules, with the possibility of hands-on activities, with FDA SMEs and Luminary Labs, LLC, staff. While the agenda is yet to be finalized, major themes will likely include FDA's testing processes and how new technologies could be employed along with instructions on how to best iterate and improve finalists' concepts, potentially including various design and innovation methodologies.
3. **Demo Day Presentation Support:** After the Boot Camp and prior to the Demo Day, all finalist teams will have the opportunity to practice their presentations and receive feedback on how to improve their Demo Day presentations.

Following Demo Day, judges will select one or more winners from the pool of finalists who will receive the remainder of the prize money.

ELIGIBILITY

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

- (a) Must have entered a submission on www.foodsafetychallenge.com, ("the Challenge website") under the rules promulgated by FDA;
- (b) Must have complied with all the requirements under this section;
- (c) 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 U.S. and maintains a primary place of business in the U.S.
- (d) 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 (USDA/FSIS), the Centers for Disease Control and Prevention (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 (BMBL), available at http://www.cdc.gov/biosafety/publications/bmbl5/.

By participating in the Challenge, each entrant agrees to comply with and abide by these Official Rules, Terms & Conditions and the decisions of FDA and/or the individual judges, which shall be final and binding in all respects.

HOW TO ENTER

To enter:

Go to the Challenge website and complete all required fields of the Challenge submission form before submission close, which is currently scheduled for November 9, 2014 at 11:59 pm EST. Each entrant must complete all of the required fields in the Challenge submission form in accordance with these Official Rules, Terms & Conditions.

All entrants are required to provide consent to these Official Rules, Terms & Conditions upon submitting an entry. Submissions must be received during the Open Submission phase of the Challenge, which officially begins after publication of a Federal Register notice announcing the Challenge, to be eligible. The Open Submission phase is to last from Challenge launch through close of open submissions, currently scheduled for 11:59 PM, November 9, 2014. Dates are subject to change. Luminary Labs, LLC, is the official timekeeper for the Challenge. Once submitted, a submission may not be altered during the Open Submission phase. During the Field Accelerator phase, the finalists will be required to provide a slide deck for their Demo Day presentation, along with a final report describing how their concept has been modified based on feedback from the FDA subject matter experts. FDA reserves the right to disqualify any submission that FDA deems inappropriate.

Entrants may enter individually or as part of a team, and teams are strongly encouraged. Each team member must be clearly identified on the team's submission form for the team to be eligible. In the event a dispute regarding the identity of the individual or team who actually submitted the entry cannot be resolved to FDA's satisfaction, the affected entry will be deemed ineligible.

All entry information and materials, including any copy of the Submission, become property of FDA and will not be acknowledged or returned. Proof of submission is not considered proof of delivery to or receipt of such entry. Furthermore, FDA and Luminary Labs, LLC, shall have no liability for any Submission that is lost, intercepted, or not received by FDA and/or Luminary Labs, LLC. FDA and Luminary Labs, LLC, assume no liability or responsibility for any error, omission, interruption, deletion, theft, destruction or unauthorized access to, or alteration of, Submissions.

REPRESENTATIONS AND WARRANTIES/INDEMNIFICATION

By participating in the Challenge, each entrant represents, warrants, and covenants as follows:

- (a) entrant is the sole author, creator, and owner of the Submission;

- (b) the Submission is not the subject of any actual or threatened litigation or claim;
- (c) the Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party;
- (d) the Submission does not and will not contain any harmful computer code (sometimes referred to as “malware,” “viruses” or “worms”); and
- (e) the Submission, and entrants’ use of the Submission, does not and will not violate any applicable laws or regulations, including, without limitation, applicable export control laws and regulations of the U.S. and other jurisdictions.

If the Submission includes any third party works (such as third party content or open source code), entrant must be able to provide, upon FDA and/or Luminary Labs, LLC’s request, documentation of all appropriate licenses and releases for such third party works. If entrant cannot provide documentation of all required licenses and releases, FDA reserves the right, in FDA’s sole discretion, to disqualify the applicable Submission, or seek to secure the licenses and releases for FDA’s benefit and allow the applicable Submission to remain in the Challenge, and reserves all rights with respect to claims based on any damages caused by participant’s failure to obtain such licenses and releases.

Entrants will indemnify, defend, and hold harmless FDA and Luminary Labs, LLC, from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from entrant’s Submission or any breach or alleged breach of any of the representations, warranties, and covenants of entrant hereunder.

FDA reserves the right to disqualify any Submission that FDA, in its discretion, deems to violate these Official Rules, Terms & Conditions.

SUBMISSION LICENSE

Each entrant retains title and full ownership in and to their Submission. Entrant expressly reserves all intellectual property rights not expressly granted under this Agreement. 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.

PUBLICITY RELEASE

By participating in the Challenge, each entrant hereby irrevocably grants to FDA and Luminary Labs, LLC, the right to use such entrant’s name, likeness, image, and biographical information in any and all media for advertising and promotional purposes relating to the Challenge, and otherwise, as stated in these Official Rules, Terms, & Conditions.

DISQUALIFICATION

FDA reserves the right in its sole discretion to disqualify any entrant who is found to be tampering with the entry process or the operation of the Challenge or Challenge website or other Challenge-related websites, to be acting in violation of these Official Rules, Terms & Conditions, or to be acting in an unsportsmanlike or disruptive manner, or with the intent to disrupt or undermine the legitimate operation of the Challenge, or to annoy, abuse, threaten, or harass any other person, and FDA reserves the right to seek damages and other remedies from any such person to the fullest extent permitted by law.

LINKS TO THIRD PARTY WEBSITES

The Challenge website may contain links to third-party websites that are not owned or controlled by Luminary Labs, LLC, or FDA. Luminary Labs, LLC, and FDA do not endorse or assume any responsibility for any such third-party sites. If an entrant accesses a third party website from the Challenge website, he/she/it does so at his/her/its own risk and expressly relieves Luminary Labs, LLC, and/or FDA from any and all liability arising from use of any third-party website content.

FINALIST AND WINNER SELECTION/EVALUATION CRITERIA

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. Examples of revolutionary techniques include (but are not limited to) metagenomics (or other next-generation sequencing methods), spectroscopy, application of nanotubes/nanotechnology, quantum detection methods, and electrical detection methods.

Concepts may combine new techniques with existing methodologies (such as PCR), and must describe where time savings are achieved in the testing process as well as expected time from unprepared food sample(s) to verifiable result(s).

A panel of expert judges will select finalist teams from the pool of eligible entries. These finalists will then refine their concept 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 evaluation criteria, with equal weighting (i.e. 20% for each):

Finalist evaluation criteria

1. 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.
2. 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.

3. Applicability: Applicability of solution to FDA testing processes.
4. Revolutionary: Whether the concept would be a revolutionary improvement over FDA's current testing procedures with potential to make a major impact on food testing.
5. Execution: Perceived ability of submitting team or individual to execute and develop their concept.

In general, submissions must describe how the technique would increase speed of pathogen detection efforts (starting from unprepared food sample, through verification of pathogen) without sacrificing specificity and sensitivity or comparability to reference methods (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm). Submitted concepts can be targeted to any point in the food system (i.e. harvest, packaging, distribution, point of sale, etc.). 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. The submission proof of concept should be comparable to the validation methods described in FDA's Methods Validation Guidelines for Microbial Pathogens (http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM273418.pdf). 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.

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 Challenge Field Accelerator phase.

The evaluation criteria are to be applied in the sole discretion of FDA and the individual judges and are subject to modification by FDA. By participating in the Challenge, each entrant into the Challenge acknowledges and agrees that such evaluations may differ from person to person and agrees to be bound by and not challenge the final decisions of FDA and the judges.

When notification of the finalists and/or winner(s) is completed, or as soon as is practical thereafter, abstracts of the submissions selected as finalists and/or winner(s) will be listed on the Challenge website for public viewing. The judging scores will not be posted. Feedback will not be provided to entrants that are not selected as finalists.

NOTICE TO FINALISTS/WINNER(s)

Attempts to notify finalists and winner(s) will be made using the contact information provided on the Challenge submission form. FDA and Luminary Labs, LLC, are not responsible for e-mail or other

communication problems of any kind.

If, despite reasonable efforts, an entrant does not respond within three (3) days of the first notification attempt regarding selection as a finalist (or a shorter time as exigencies may require), or if the notification is returned as undeliverable to such entrant, that entrant may forfeit his, her or its finalist status and an alternate finalist may be selected.

If, despite reasonable efforts, a potential winner does not respond within three (3) days of the first notification attempt (or a shorter time as exigencies may require), or if the notification of prize or the prize itself is returned as unclaimed or undeliverable to such participant, that participant may forfeit his, her or its prize and an alternate winner may be selected.

If any potential prize winner is found to be ineligible, or has not complied with these Official Rules, Terms & Conditions or declines the applicable prize for any reason prior to award, such potential prize winner will be disqualified and an alternate winner may be selected, or the applicable prize may go unawarded.

ATTENDANCE

To maintain eligibility, any selected finalists are required to participate in Challenge activities organized by FDA and Luminary Labs, LLC, which include Boot Camp and Demo Day. The winner(s) are required to attend the Winner Announcement. If an entrant is unable to participate in any mandatory activities, they will not be eligible to win the Challenge. Finalists and winner(s) are required to attend these events at their own expense.

INTELLECTUAL PROPERTY

Entrants retain ownership of their concepts, including any software, research or other intellectual property ("IP") that they develop in connection therewith, subject to the license granted to FDA to use Publicly Posted Materials as set forth herein.

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:

1. 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
2. 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.

PRIZES

The total prize pool for the Challenge is $500,000. Following the open submission phase, judges will select the finalist(s) who will receive $20,000 each. After the Field Accelerator phase and final judging, the winner(s) will receive the remainder of the prize money.

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.

DATES/DEADLINES

FDA reserves the right to modify any dates or deadlines set forth in these Official Rules, Terms & Conditions or otherwise governing the Challenge.

CHALLENGE TERMINATION

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

GENERAL LIABILITY RELEASE

By participating in the Challenge, each entrant hereby agrees that FDA and Luminary Labs, LLC,

- (a) shall not be responsible or liable for any losses, damages, or injuries of any kind (including death) resulting from participation in the Challenge or any Challenge-related activity, or from entrants' acceptance, receipt, possession, use, or misuse of any prize; and
- (b) entrants will indemnify, defend, and hold harmless FDA and Luminary Labs, LLC, from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from entrant's participation in the Challenge.

Without limiting the generality of the foregoing, FDA and Luminary Labs, LLC, are not responsible for incomplete, illegible, misdirected, misprinted, late, lost, postage-due, damaged, or stolen entries or prize notifications; or for lost, interrupted, inaccessible, or unavailable networks, servers, satellites, Internet Service Providers, websites, or other connections; or for miscommunications, failed, jumbled, scrambled, delayed, or misdirected computer, telephone, cable transmissions or other communications; or for any technical malfunctions, failures, difficulties, or other errors of any kind or nature; or for the incorrect or inaccurate capture of information, or the failure to capture any information.

These Official Rules, Terms & Conditions cannot be modified except by FDA. The invalidity or unenforceability of any provision of these Official Rules, Terms & Conditions shall not affect the validity or enforceability of any other provision. In the event that any provision is determined to be invalid or

otherwise unenforceable or illegal, these Official Rules, Terms & Conditions shall otherwise remain in effect and shall be construed in accordance with their terms as if the invalid or illegal provision were not contained herein.

EXERCISE

The failure of FDA to exercise or enforce any right or provision of these terms and conditions shall not constitute a waiver of such right or provision.

GOVERNING LAW

All issues and questions concerning the construction, validity, interpretation, and enforceability of these Official Rules, Terms & Conditions shall be governed by and construed in accordance with U.S. Federal law as applied in the Federal courts of the District of Columbia if a complaint is filed by any party against FDA, and the laws of the State of New York as applied in the New York state courts in New York City if a complaint is filed by any party against Luminary Labs, LLC.

PRIVACY POLICY

By participating in the 2014 FDA Food Safety Challenge, entrants hereby agree to collection and usage of their personal information by FDA and Luminary Labs, LLC, and acknowledge that they have read and accepted the privacy policy at www.foodsafetychallenge.com/privacy.

WINNERS LIST/OFFICIAL RULES/CONTACT

To obtain a list of finalists and winner(s) (after the conclusion of the Challenge) or a copy of these Official Rules, Terms & Conditions, send a self-addressed envelope with the proper postage affixed to: Luminary Labs, LLC, 30 West 22nd St., Floor 6, New York City, NY, 10010. Please specify “Winners List” or “Official Rules” and the name of the specific Challenge in your request.

Please contact us at info@foodsafetychallenge.com should you have any comments or questions about these Rules, Terms & Conditions.