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]

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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

with premarket review regulations and performance standards under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) would be impractical.

Effective on July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures applicable to custom devices, addressing, among other things:

- Devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type not to exceed five units per year qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, devices that qualify for the custom device exemption were clarified to include no more than ''five units per year of a particular device type'' that otherwise meet all the requirements necessary to qualify for the custom device exemption. In this guidance, FDA interprets the five units in terms of five new custom devices per year (*i.e.,* five new patients for the patient-focused custom device or five new physicians for the physician-focused custom device, assuming all other required elements for the custom device exemption are satisfied). The five-unit limitation includes all devices provided by a manufacturer to, and remaining in the possession of, the ordering physician and/or patient.

The guidance defines terms used in the custom device exemption, explains how FDA plans to interpret the term ''five units per year of a particular device type'' set forth in section 520(b)(2)(B) of the FD&C Act, describes what information manufacturers should submit in a custom device annual report to FDA, and provides guidance on how to submit an annual report for devices distributed under the custom device exemption.

On January 14, 2014, FDA issued the draft guidance entitled ''Custom Device Exemption'' (Ref. 1). The Agency has reviewed the comments submitted for the draft guidance and has incorporated many of the recommendations in this final guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on custom devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Custom Device Exemption,'' you may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1820 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The collections of information in 21 CFR 814, subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of custom device annual reporting have been approved under OMB control number 0910–0767.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. The FDA draft guidance entitled ''Custom Device Exemption,'' available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380497.pdf.*

Dated: September 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22683 Filed 9–23–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1352]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH GL52); Draft Guidance for Industry on Bioequivalence: Blood Level Bioequivalence Study; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #224) entitled ''Draft Guidance for Industry, Bioequivalence: Blood Level Bioequivalence Study'' (VICH GL52). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to harmonize the data recommendations associated with in vivo blood level bioequivalence (BE) for veterinary pharmaceutical products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 24, 2014.