

comment period for the draft guidance until January 4, 2010. The agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying finalization of this level 1 guidance.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: October 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-26636 Filed 11-2-09; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0348]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 4, 2010, the comment period for the draft guidance entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens" that appeared in the **Federal Register** of August 3, 2009 (74 FR 38439), as corrected on August 21, 2009 (74 FR 42311). In the notice of availability, FDA requested comments by November 2, 2009. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written or electronic comments by January 4, 2010.

ADDRESSES: Submit electronic comments 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.

FOR FURTHER INFORMATION CONTACT:

Amy Green, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 301-436-2025.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 3, 2009 (74 FR 38439), as corrected on August 21, 2009 (74 FR 42311), FDA published a notice of availability with a 90-day comment period to request comments on the draft guidance entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens" (the draft guidance). Comments on the draft guidance will inform FDA's current thinking for finalization of this Level 1 guidance consistent with FDA's good guidance practices.

The agency has received requests for an extension of the comment period for the draft guidance. FDA has considered the requests and is extending the comment period for the draft guidance until January 4, 2010. The agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying finalization of this Level 1 guidance.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: October 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Live-Attenuated Tularemia Vaccine

Description of Invention: The invention provides compositions and methods of use for a modified strain of *Francisella tularensis*, the causative agent of tularemia, a category A biodefense agent (NIAID classification). Currently, no vaccines are available, and the only approved therapeutics for tularemia are antibiotics that are only effective if delivered early in the infection. The subject invention defines and characterizes mutations in *Francisella tularensis* that result in attenuated bacteria capable of inducing strong protective immune responses. Thus, these stable mutant strains could be used as efficient live vaccines against tularemia.

Applications: Live-attenuated vaccines against *Francisella tularensis*.

Advantages:

- Live-attenuated bacteria can be easily produced through recombinant technologies
- Live-attenuated vaccines do not require adjuvants
- Immune response to live-attenuated vaccines lasts for years and does not require booster

Development Status: In vitro and in vivo data available.