comment period for the draft guidance until January 4, 2010.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]

BILLING CODE 4160–01–S

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Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending to January 4, 2010, the comment period for the draft guidance entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens'' that appeared in the **Federal Register** of August 3, 2009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.

[FR Doc. E9–26637 Filed 11–2–09; 11:15 am]

BILLING CODE 4160–01–S

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 no 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.

Inventors: Jean A. Celli and Catharine M. Bosio (NIAID).

Relevant Publications:

1. TD Wehrly *et al.* Intracellular biology and virulence determinants of Francisella tularensis revealed by transcriptional profiling inside macrophages. Cell Microbiol. 2009 Jul;11(7): 1128–1150.
2. J Su *et al.* Genome-wide identification of Francisella tularensis virulence determinants. Infect Immun. 2007 Jun;75(6):3089–3101.
3. S Janovská *et al.* Identification of immunoreactive antigens in membrane proteins enriched fraction from Francisella tularensis LVS. Immunol Lett. 2007 Feb 15;108(2):151–159.
4. S Janovská *et al.* Proteomic analysis of antibody response in a case of laboratory-acquired infection with Francisella tularensis subsp. tularensis. Folia Microbiol (Praha). 2007;52(2):194–198.

Patent Status: U.S. Provisional Application No. 61/156,173 filed 27 Feb 2009 (HHS Reference No. E–125–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Sally Hu, Ph.D.; 301–435–5606; *HuS@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID Office of Technology Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize live vaccine strains of *Francisella tularensis* with defined mutations. Please contact Rosemary Walsh at 301–496–2644 for more information.

Improved Targeting Precision of Radiotherapy

Description of Invention: The technology offered for licensing is in the field of radiotherapy. The invention provides for improvement in the targeting precision of 4D Image-Guided Radiation Therapy (4D IGRT). It relates to new methods for (1) predicting the dynamic tidal volume of a patient and (2) predicting the motion of the diaphragm and points of interest near the diaphragm, by monitoring the external volume change of a patient's torso, thereby improving the time-resolved computed tomography (4DCT) and motion-compensated radiation therapy (4DRT). The method is based on the observation that the change in torso volume is representative of the change in lung air volume (expansion and contraction) driven by diaphragm displacement, as evidence by the high linear relationship between the two with a linear coefficient of unity. A model of lung volume expansion and extension within a patient's rib cage is presented in this invention to convert the external torso volume change (TVC) to relative diaphragm displacement.

Applications: The method can be integrated with Image-Guided Radiation Therapy and related instrumentation to provide improvement in targeting precision and thus enhancement in therapeutic ratio and radiotherapy outcome.

Advantage: The invention is advantageous to previous methods related to tracking of internal organ motion due to its unique observations as follows:

- There is a highly correlated, quantitative linear relationship between volume changes of the external torso and the internal lung during respiration.
- Based on this external-internal volumetric relationship and lung volume compensation model, a patient's diaphragm displacement can be predicted with a clinically acceptable accuracy.

A novel approach based on these observations may therefore offer a more accurate and reliable approach for motion tracking during 4D IGRT, in comparison to existing methods. In particular, the advantages which may be provided by this technology are as follows:

- Minimizing the use of excessive ionization radiation for patient imaging. The use of x-ray based imaging techniques can be largely avoided.
- Minimizing the use of intrusive implanted fiducials for target localization, a method currently used in radiation therapy.
- Torso volume change is more comprehensive indication of lung volume change than the fiducial displacement or bellows tension, which are both indirect indicators. This approach intrinsically eliminates the problems due to sensitivity of marker location, reproducibility of marker(s) placement, complexity of data analysis, and reliability of motion correlation in the presence of breathing irregularity and breathing pattern change.
- The technology may be advantageous to the currently used spirometry method, which requires frequent calibration, baseline drift calibration and inconvenience.
- The technology can be utilized by modifying existing superficial imaging techniques, such as optical camera imaging (OCI) systems. Therefore it is highly likely that the technology can be integrated into an image guided radiation therapy in the future.

Development Status: The core of this invention is established. The following 2 on-going studies have been initiated: (1) Calculating the motion of a tumor anywhere in the lungs using a tumor motion model and volumetric boundary conditions, and (2) calculating the volumes using a surface imaging system and testing the accuracy based on phantom and patient studies. The implementation of this technique after the studies should be straightforward in an existing radiotherapy system.

Market: The commercial market of radiotherapy and related equipment is huge. Radiotherapy alone or in combination with chemotherapy is used for at least 50% of cancer treatments. According to market research the radiation therapy market is growing rapidly with annual cancer rates worldwide projected to increase by fifty percent by 2020. Extra-cranial stereotactic body radiotherapy (SBRT) using ablative or near ablative radiation dose to the tumor has shown significant improvement in local control rate, especially in early stage of non-small cell lung cancer (NSCLC). The requirement for high precision motion monitoring and tracking is critical for SBRT procedures with clinically tolerable toxicity to normal tissues.

Methods of calculating internal organ motion are incorporated into radiotherapy systems to enhance their targeting precision and improve therapeutic ratio. The market for these methods is therefore vast and rapidly growing. In particular, there is a constant need for such improved methods that can readily be integrated into existing systems. The invention described here has therefore a good potential for commercial success.

Inventors: Guang (George) Li (NCI), Robert W. Miller (NCI), Kevin A. Camphausen (NCI), *et al.*

Patent Status: U.S. Provisional Application No. 61/145,487 filed 16 Jan 2009 (HHS Reference No. E–151–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., MBA; 301–435–4616; *UR7a@nih.gov*; John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov*.

A Novel Multimeric CD4 Fusion Protein for Treating HIV Infection

Description of Invention: This invention could potentially provide an alternative to antiretroviral therapy (ART), especially in cases where productively-infected cells persist with ART. This multimeric CD4 fusion protein acts as a decoy to inhibit human immunodeficiency virus (HIV–1) entry

into host cells. More specifically, this multimeric CD4 inhibits the interaction between HIV–1 gp120 and CD4 present on the surface of CD4 T-cells, the major HIV–1 target cell. There is strong evidence that binding between gp120, as part of a virion spike, and CD4 on cell surface is the first step for HIV entry into host cells. This multimeric CD4 provides a number of advantages over inhibitory CD4 molecules previously developed. First, this CD4 multimer is capable of binding at least 10 gp120 simultaneously with high avidity. Second, it does not enhance HIV infection at suboptimal concentrations, a phenomenon observed with previously developed recombinant CD4 molecules. Third, it has been demonstrated that this CD4 fusion protein hyper-crosslinks CD16 on natural killer (NK) cells and as a consequence delivers an exceptionally strong signal to NK cells, promoting potent Antibody-Dependent Cellular Cytotoxicity (ADCC) and lysis of HIV-infected cells. The inventors have shown that this recombinant CD4 multimer efficiently neutralizes primary isolates from different HIV subgroups.

The invention comprises an immunoglobulin construct having up to 12 amino terminal domains of CD4 (D1D2), the epitope responsible for HIV–1 gp120 binding activity. It also comprises domains of a human IgG1 heavy chain, as well as the IgA tailpiece that drives its polymerization. The two amino terminal domains of CD4 are fused to the CH2CH3 domains (which bears the FC receptor recognition epitopes) of a human IgG1 heavy chain.

Applications: HIV therapeutics and HIV vaccine development.

Advantages: Efficient inhibition of HIV–1 viral entry without enhancement of infection at suboptimal concentrations. Potent activation of Antibody-Dependent Cellular Cytotoxicity (ADCC) and lysis of HIV-infected cells.

Development Status: The anti-HIV activity of this multimeric CD4 protein has been well characterized in vitro.

Inventors: James Arthos, Claudia Cicala, Anthony S. Fauci (NIAID).

Publications:

1. J Arthos *et al.* Biochemical and biological characterization of a dodecameric CD4–Ig fusion protein: implications for therapeutic and vaccine strategies. J Biol Chem. 2002 Mar 29;277(13):11456–11464.
2. PD Kwong *et al.* HIV–1 evades antibody-mediated neutralization through conformational masking of receptor-binding sites. Nature. 2002 Dec 12;420(6916):678–682.
3. N Gupta *et al.* Targeted lysis of HIV-infected cells by natural killer cells armed and triggered by a recombinant immunoglobulin fusion protein: implications for immunotherapy. Virology. 2005 Feb 20;332(2):491–497.
4. T Zhou *et al.* Structural definition of a conserved neutralization epitope on HIV–1 gp120. Nature. 2007 Feb 15;445(7129):732–737.
5. A Bennett *et al.* A Cryoelectron tomographic analysis of an HIV-neutralizing protein and its complex with native viral gp120. J Biol Chem. 2007 Sep 21;282(38):27754–27759.

Patent Status: HHS Reference No. E–337–2001/0—

- U.S. Patent No. 7,368,114 issued 06 May 2008
- European Application No. 02799169.4 (recently allowed)

Licensing Status: Available for licensing.

Licensing Contact: RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Immunoregulation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this invention. Please contact William Ronnenberg at 301–451–3522 or *wronnenberg@niaid.nih.gov* for more information.

Dated: October 29, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–26607 Filed 11–3–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Development and Social Psychology.

Date: November 12, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Lee S. Mann, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0677, *mannl@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 28, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26576 Filed 11–3–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(6), as amended. The discussions could disclose personal information concerning NCI Staff and/or its contractors, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.