

soluble antigen, to a mucosal surface. The soluble antigens can be full length, naturally occurring polypeptides or fragments (*i.e.* peptides) derived from them. The soluble antigen is administered with an adjuvant at the mucosal site or without an adjuvant. Adjuvants can be, for example, Cholera toxin (CT), mutant CT (MCT), *E. coli* heat labile enterotoxin (LT) and others. Cytokines like IL-12 or IFN γ can also be administered to enhance the immunoreactivity. Mucosal routes of administration include intrarectal (IR), intranasal (IN), intragastric (IG), intravaginal (IVG) or intratracheal (IT). Soluble antigens can be derived from pathogenic viruses (*e.g.* HIV, influenza, or hepatitis virus), bacteria (*e.g.* *Listeria monocytogenes*), or protozoans. Furthermore, the soluble antigen can be tumor-associated antigen for cancer applications.

The utility of the technology has been extensively demonstrated when applied to HIV. Details about the HIV studies are provided in the eight (8) publications cited below.

Applications

- Immunization to treat infectious diseases.
- Possible applications in cancer therapy.

Development Status: Proof of concept has been demonstrated, in particular as related to HIV.

Inventors: Jay A. Berzofsky (NCI) *et al.*

Relevant Publications

1. Belyakov IM, Derby MA, Ahlers JD, Kelsall BL, Earl P, Moss B, Strober W, Berzofsky JA. Mucosal immunization with HIV-1 peptide vaccine induces mucosal and systemic cytotoxic T lymphocytes and protective immunity in mice against intrarectal recombinant HIV-vaccinia challenge. *Proc Natl Acad Sci USA*. 1998 Feb 17;95(4):1709-1714. [PubMed: 9465081]

2. Belyakov IM, Ahlers, JD, Brandwein BY, Earl P, Kelsall B, Moss B, Strober W, Berzofsky JA. The importance of local mucosal HIV-specific CD8+ cytotoxic T lymphocytes for resistance to mucosal viral transmission in mice and enhancement of resistance by local administration of IL-12. *J Clin Invest*. 1998 Dec 15;102(12):2072-2081. [PubMed: 9854042]

3. Belyakov IM, Ahlers JD, Clements JD, Strober W, Berzofsky JA. Interplay of cytokines and adjuvants in the regulation of mucosal and systemic HIV-specific CTL. *J Immunol*. 2000 Dec 1;165(11):6454-6462. [PubMed: 11086085]

4. Belyakov IM, Hel Z, Kelsall B, Kuznetsov VA, Ahlers JD, Nacsa J, Watkins DI, Allen TM, Sette A, Altman J, Woodward R, Markham PD, Clements JD, Franchini G, Strober W, Berzofsky JA. Mucosal AIDS vaccine reduces disease and viral load in gut reservoir and blood after mucosal infection of macaques. *Nat Med*. 2001 Dec;7(12):1320-1326. [PubMed: 11726972]

5. Belyakov IM, Kuznetsov VA, Kelsall B, Klinman D, Moniuszko M, Lemon M, Markham PD, Pal R, Clements JD, Lewis MG, Strober W, Franchini G, Berzofsky JA. Impact of vaccine-induced mucosal high avidity CD8+ CTLs in delay of AIDS-viral dissemination from mucosa. *Blood* 2006 Apr 15;107(8):3258-3264. [PubMed: 16373659]

6. Belyakov IM, Isakov DV, Zhu Q, Dzutsev A, Berzofsky JA. A novel functional CTL avidity/activity compartmentalization to the site of mucosal immunization contributes to protection of macaques against simian/human immunodeficiency viral depletion of mucosal CD4+ T cells. *J Immunol*. 2007 Jun 1;178(11):7211-7221. [PubMed: 17513770]

7. Belyakov IM, Ahlers JD, Nabel GJ, Moss B, Berzofsky JA. Generation of functionally active HIV-1 specific CD8+ CTL in intestinal mucosa following mucosal, systemic, or mixed prime-boost immunization. *Virology* 2008 Nov 10;381(1):106-115. [PubMed: 18793787]

8. Sui Y, Zhu Q, Gagnon S, Dzutsev A, Terabe M, Vaccari M, Venzon D, Klinman D, Strober W, Kelsall B, Franchini G, Belyakov IM, Berzofsky JA. Innate and adaptive immune correlates of vaccine and adjuvant-induced control of mucosal transmission of SIV in macaques. *Proc Natl Acad Sci USA*. 2010 May 25;107(21):9843-9848. [PubMed: 20457926]

Patent Status: HHS Reference No. E-268-1997/2—

- U.S. Patent Application No. 09/508,552, which issued as U.S. Patent No. 6,749,856 on 15 Jun 2004.
- Foreign patents issued in Australia (Application Number 93862/98 and Patent Number 757310) and in European countries (Application Number 98946965.5 and Patent Number 1011720); Germany, France, Ireland, United Kingdom, Italy, Portugal and Spain.
- Divisional U.S. Patent Application No. 10/815,340 filed 30 Mar 2004.

Licensing Status: Available for licensing and commercial development.

Licensing Contacts: Uri Reichman, PhD, MBA; 301-435-4616; UR7a@nih.gov; or John Stansberry, PhD; 301-435-5236; js852e@nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research, Vaccine Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Mucosal Cytotoxic T Lymphocyte Responses. Please contact John D. Hewes, PhD at 301-435-3121 or hewes@mail.nih.gov for more information.

Dated: August 31, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010-22182 Filed 9-3-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0426]

Draft Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)” dated August 2010. This draft guidance provides you, manufacturers of a licensed vaccine, with advice concerning compliance with the bar code label requirements. In this guidance, FDA is proposing to amend our response to question 12 (Q12) in the “Bar Code Label Requirements—Questions and Answers” guidance dated October 2006 (Bar Code Guidance), to provide recommendations to manufacturers of licensed vaccines in connection with the use of alternative coding technologies. When this guidance is finalized, we intend to incorporate the revised response to Q12 into the Bar Code Guidance, but otherwise continue with our recommendations for bar code label requirements as currently provided in the Bar Code Guidance.

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 8, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)" dated August 2010. FDA regulations require that certain human drug and biological product labels contain a bar code (§ 201.25 (21 CFR 201.25)). This draft guidance provides you, manufacturers of a licensed vaccine, with advice concerning compliance with the bar code label requirements. Previously, FDA issued questions and answers regarding how the bar code label requirements apply to specific products or circumstances in the Bar Code Guidance (October 5, 2006, 71 FR 58739). In this guidance, FDA is proposing to amend our response to question 12 (Q12) in the Bar Code Guidance to provide recommendations to manufacturers of licensed vaccines in connection with the use of alternative coding technologies. We are revising our response because we believe that an alternative regulatory program, comprised of alternative technology such as two dimensional symbology, could render the use of linear bar codes unnecessary for patient safety and could enhance health care providers' ability to comply with the National Childhood

Vaccine Injury Act of 1986 (Public Law 99-660) (42 U.S.C. 300aa-25(a)). We would consider granting a request for exemption to the bar code requirement under § 201.25(d)(ii) in connection with such use.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. The collection of information in 21 CFR part 201 has been approved under OMB control number 0910-0537.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-22169 Filed 9-3-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

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 meetings.

The meetings 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: National Institute of Mental Health Special Emphasis Panel; ITVC Conflicts.

Date: October 6, 2010.

Time: 11 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Enid Light, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6132, MSC 9608, Bethesda, MD 20852, 301-443-3599, elight@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; K99.

Date: October 18, 2010.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609, 301-402-6807, libbey@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: August 31, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-22185 Filed 9-3-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

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