DEPARTMENT OF HEALTH AND HUMAN SERVICES

Support, Training and Capacity Building for Infectious Disease Surveillance Networks in Affected Countries in Southeast Asia, Africa and Other Regions of the World

AGENCY: Office of Public Health Emergency Preparedness, Office of the Secretary, HHS.

ACTION: Notice; Correction.

SUMMARY: The Office of Public Health Emergency Preparedness, HHS, published a notice in the **Federal Register** on Wednesday, March 8, 2006 announcing a forthcoming single source cooperative agreement award to the Pasteur Foundation, a not-for-profit affiliate of the Institut Pasteur to enhance the surveillance, epidemiological investigation and laboratory diagnostic capabilities in countries in S.E. Asia, Africa and other regions of the world. That notice contained an error by having omitted certain amounts of funding for enhancement of laboratory capacity at Institut Pasteur-Cambodia (IPC) in the second and third year of the project, for a virologist for IPC for three years, and for a senior project manager to coordinate the activities across the different countries that are involved in this project. This notice corrects the omission.

FOR FURTHER INFORMATION CONTACT: Lily O. Engstrom, 202–205–2882.

Correction

In the **Federal Register** of March 8, 2006, in FR Vol. 71, No. 45, on page 11665, correct the table to add the following omissions:

$440,000 for enhancement of laboratory capacity at IPC for Year 2 and Year 3 ($220,000 per year); $210,000 for a virologist for IPC for three years ($70,000 per year); and $450,000 for a project manager for three years ($150,000 per year).

The cooperative agreement resulting from this Funding Opportunity will be fully funded this fiscal year.

Dated: April 26, 2006.

Stewart Simonson,

Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services.

[FR Doc. E6–6595 Filed 5–1–06; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Mine Safety and Health Research Advisory Committee (MSHRAC).

Times and Dates: 9:00 a.m.–4:30 p.m., May 23, 2006. 8:30 a.m.–12:30 p.m., May 24, 2006.

Place: Four Points Hotel by Sheraton, 1201 K Street, NW., Washington, DC, 20005, telephone (202) 289–7600, fax (202) 289–3310.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This committee is charged with providing advice to the Secretary, Department of Health and Human Services, the Director, CDC, and the Director, National Institute for Occupational Safety and Health (NIOSH), on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

Matters to be Discussed: The meeting will focus on NIOSH's current and planned research and prevention activities related to mine disaster prevention and response. The agenda will also include updates on partnership activities and reports from the Director and Associate Director.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Jeffery L. Kohler, Ph.D., Executive Secretary, MSHRAC, NIOSH, CDC, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, Pennsylvania 15236, telephone (412) 386–5301, fax (412) 386–5300.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 24, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–6649 Filed 5–1–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0169]

Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under the Federal Food, Drug, and Cosmetic Act'' (the act). The guidance explains FDA's current thinking on the labeling of certain uses of lecithin derived from soy under the act. This guidance is part of FDA's implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA).

DATES: This guidance is final upon the date of publication. Submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Additive Safety (HFS–205), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1200, FAX: 301–436–2972. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Paul M. Kuznesof, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1289, or e-mail: *paul.kuznesof@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled

''Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act.'' This guidance is part of FDA's implementation of FALCPA (Public Law 108–282). If a food is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains a major food allergen, the food must comply with section 403(w) of the act (21 U.S.C. 343(w)). Section 403(w)(1) requires that the food's label declare the name of the food source from which the major food allergen is derived in a manner specified by that section. This source declaration requirement is extended by section 403(w)(4) to any incidental additive that is, or that bears or contains, a major food allergen, notwithstanding the regulatory exemption for incidental additives in 21 CFR 101.100(a)(3). The requirements of section 403(w) of the act apply to foods labeled on or after January 1, 2006.

II. Discussion

The purpose of the guidance document is to provide guidance to the industry on the labeling, under section 403(w) of the act, of certain uses of lecithin derived from soy in packaged foods. In particular, as discussed in the guidance, FDA intends to consider the exercise of enforcement discretion for a packaged food labeled on or after January 1, 2006, in which lecithin derived from soy is used solely as a component of a release agent and the label for such food does not declare the presence of the lecithin consistent with the requirements of section 403(w). FDA intends to consider exercising such discretion when all of the factors discussed in the guidance are present.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, foods labeled on or after January 1, 2006, must comply with section 403(w) of the act's labeling requirements.

This guidance represents the agency's current thinking on the labeling of certain uses of lecithin derived from soy under section 403(w) of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments ortwo 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. The guidance and 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 guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: April 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6551 Filed 5–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0170]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports (VICH GL42); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#182) entitled ''Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports'' (VICH GL42). 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). The objective of this draft guidance document is to standardize the data for submission of adverse events relating to veterinary medicinal products.

DATES: Submit written or electronic comments on the draft guidance by June 1, 2006, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Post, Center for Veterinary Medicine, (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9062, e-mail: *lynn.post@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval