

the halogenated gases (chloroform, trichloroethylene, halothane, methoxyflurane, fluroxene, and enflurane) was established in 1977 [NIOSH 1977]. The halogenated anesthetic agents, isoflurane, desflurane, and sevoflurane, were subsequently introduced and are not included in the 1977 NIOSH recommendation. Isoflurane, desflurane, and sevoflurane are commonly used for anesthesia in modern hospitals; however, no occupational exposure limits exist for these agents. NIOSH is requesting: (1) Comments and information relevant to the evaluation of health risks associated with occupational exposure to isoflurane, desflurane, and sevoflurane, (2) reports or other data that demonstrate adverse health effects in workers exposed to isoflurane, desflurane, and sevoflurane, and (3) information pertinent to establishing a REL for isoflurane, desflurane, and sevoflurane.

**ADDRESSES:** Comments should be transmitted to the NIOSH Docket Office, M/S C-34, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533-8303, fax: 513/533-8285.

Comments may also be submitted directly through the Web site (<http://www.cdc.gov/niosh/review/public/Waste-Anesthetic-Gases/>), by e-mail to [nioshdocket@cdc.gov](mailto:nioshdocket@cdc.gov), or by fax to 513/533-8285. E-mail attachments should be formatted as Microsoft Word. Comments concerning this notice must be received on or before April 18, 2006 and should reference docket number NIOSH-064.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**FOR FURTHER INFORMATION CONTACT:** Henryka Nagy, Ph.D., M/S C-32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533-8369, e-mail [HUB1@cdc.gov](mailto:HUB1@cdc.gov).

**SUPPLEMENTARY INFORMATION:** During patient anesthetization, small amounts of anesthetic gases can escape from the anesthetic delivery system and the patient's respiratory system. Waste anesthetic gases may become a source of harmful exposures for operating room personnel.

Anesthesiologists, veterinarians, dentists, anesthetic nurses, operating room nurses, surgeons, operating room technicians, and other operating room personnel are at risk of exposure to waste anesthetic gases. A concern about

harm to the reproductive system, central nervous system, liver, and kidneys prompted NIOSH to develop RELs for waste anesthetic gases [NIOSH 1977]. In 1977, the current NIOSH REL of 2 parts per million (ppm) as a 60-minute ceiling was established for the halogenated gases chloroform, trichloroethylene, halothane, methoxyflurane, fluroxene, and enflurane [NIOSH 1977]. Isoflurane, desflurane, and sevoflurane were subsequently introduced and are not included in the 1977 NIOSH recommendation.

NIOSH has not yet developed RELs for isoflurane, desflurane, and sevoflurane. Furthermore, the Occupational Safety and Health Administration (OSHA) has no permissible exposure limits (PELs) for these agents. The Netherlands' 1998 Dutch Expert Committee on Occupational Standards (DECOS) derived an occupational exposure limit of 20 ppm for enflurane on the basis of reproductive toxicologic data [DECOS 1998]. For isoflurane (an isomer of enflurane), DECOS also recommended an occupational exposure limit of 20 ppm on the basis of assumed structure-related activity [DECOS 1998]. No epidemiologic studies are available on the health effects of the halogenated agents, isoflurane, desflurane, and sevoflurane.

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to these gases. Examples of requested information include, but are not limited to, the following: (1) Identification of industries or occupations in which exposures to isoflurane, desflurane, or sevoflurane may occur; (2) trends in production and use of isoflurane, desflurane, or sevoflurane over the past 10 years; (3) descriptions of procedures with a potential for exposure to isoflurane, desflurane, or sevoflurane; (4) current occupational exposure concentrations of isoflurane, desflurane, or sevoflurane in various types of occupational scenarios and, if available, data to document these concentrations (5) case reports or other health data that demonstrate adverse health effects in workers exposed to isoflurane, desflurane, or sevoflurane, or animal data (published or peer-reviewed data are preferred); (6) descriptions of work practices and engineering controls used to reduce or prevent workplace exposure; (7) educational materials for worker safety or training on the safe handling of these halogenated agents; (8) data pertaining to the technical feasibility of establishing a more

protective REL for isoflurane, desflurane, and sevoflurane.

NIOSH will use this information to determine the need for developing recommendations for reducing occupational exposure to isoflurane, desflurane, and sevoflurane.

*References:* DECOS [1998]. Enflurane, isoflurane and cyclopropane: health-based recommended occupational exposure limits. Report of the Dutch Expert Committee on Occupational Standards, a committee of the Health Council of the Netherlands.

NIOSH [1977]. Criteria for a recommended standard \* \* \* occupational exposure to waste anesthetic gases and vapors. Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 77-140.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 14, 2006.

**Alvin Hall,**

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

[FR Doc. 06-1542 Filed 2-17-06; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0488]

#### Animal Drug User Fee Act; Public Meeting; Cancellation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is canceling the meeting on the Animal Drug User Fee Act scheduled for February 24, 2006. This meeting was announced in the **Federal Register** of December 28, 2005 (70 FR 76851). FDA will continue to seek public comments relative to the program's overall performance and reauthorization as directed by Congress. FDA will publish another notice in the **Federal Register** announcing any plans for rescheduling the public meeting.

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** You may submit written comments 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>. Follow the instructions for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, FAX: 240-276-9020, e-mail: [aleta.sindela@fda.hhs.gov](mailto:aleta.sindela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** If you would like to submit written comments to the docket regarding the Animal Drug User Fee Act, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written 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 reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06-1571 Filed 2-15-06; 2:42 pm]

**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.

#### Methodology for Large Scale Manufacture of Stable Disulfide-Conjugated Antibody-Ribonuclease

David F. Nellis, Dianne L. Newton, Susanna M. Rybak (NCI)  
U.S. Provisional Application filed 30 Sep 2005 (HHS Reference No. E-218-2005/0-US-01)

*Licensing Contact:* David A. Lambertson; 301/435-4632; [lambertson@mail.nih.gov](mailto:lambertson@mail.nih.gov)

Large scale clinical production of disulfide-conjugated antibody-RNase therapeutics using previously reported technologies usually results in an unstable product that forms undesired multimeric antibody/RNase species. This invention describes improved methods for the large scale manufacture of stable disulfide-conjugated antibody therapeutics. Antibody-RNase conjugates produced by this method were specific and highly active in vitro in killing selected carcinoma, and also showed in vivo activity in the treatment of disseminated B-cell lymphoma. These methods are broadly applicable to disulfide-linked conjugation of cytotoxic proteins. The claims for this invention encompass methods for preparing a protein for disulfide conjugation with another molecule, such as an RNase to an antibody.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### Identification of Biomarkers by Serum Protein Profiling

Thomas Ried and Jens Habermann (NCI)  
U.S. Provisional Application No. 60/664,681 filed 22 Mar 2005 (HHS Reference No. E-106-2005/0-US-01)

*Licensing Contact:* Thomas P. Clouse; 301/435-4076; [clouset@mail.nih.gov](mailto:clouset@mail.nih.gov)

This invention describes serum features that distinguish colorectal carcinoma malignant patient samples versus healthy samples using surface-enhanced laser desorption ionization time-of-flight (SELDI-TOF) mass spectrometry. By comparing healthy versus malignant samples, the investigators were able to identify thirteen (13) serum features that have been validated using an independently collected, blinded validation set of 55 sera samples. The features are

characterized by the mass to charge ratio (m/z ratio). The investigators have shown that SELDI-TOF based serum marker protein profiling enables minimally invasive detection of colon cancer with 96.7 percent sensitivity and 100 percent specificity.

Colorectal cancer is the third most common cancer and the third leading cause of cancer-related mortality in the United States. Current diagnostic methods for colorectal cancer have a large non-compliance rate because of discomfort, e.g., sigmoidoscopy or colonoscopy, or have a high rate of false positive results, e.g., fecal occult blood tests. The claimed invention has the potential to be a widely used, easy-to-use, and inexpensive diagnostic.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### Novel Form of Interleukin-15, Fc-IL-15, and Methods of Use

Morihiro Watanabe *et al.* (NCI)  
U.S. Provisional Application No. 60/670,862 filed 12 Apr 2005 (HHS Reference No. E-296-2004/0-US-01)  
*Licensing Contact:* Thomas P. Clouse, J.D.; 301/435-4076; [clouset@mail.nih.gov](mailto:clouset@mail.nih.gov)

Interleukin-15 (IL-15) is a potent cytokine that enhances host immune system function by proliferating and activating leukocytes. IL-15 increases innate immunity and CD8 memory. The investigators fused IL-15 with protein Fc, a fragment of immunoglobulin. The new fused moiety, Fc-IL-15, has a longer half life in vivo than naturally occurring IL-15 in a gene therapy setting and has more potent anti-tumor effects than IL-15 in some mouse tumor models. The new moiety can serve as an alternative to IL-15, particularly if long term delivery is essential for a therapy. The moiety can serve as a therapeutic for both tumors and viral infections. The moiety can include peptide linkers such as, for example, a T cell inert sequence or a non-immunogenic sequence.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

#### ELISA Assay of Serum Soluble CD22 To Assess Tumor Burden/Relapse in Subjects with Leukemia and Lymphoma

Robert J. Kreitman *et al.* (NCI)  
U.S. Patent Application No. 10/514,910 filed 16 Nov 2004 (HHS Reference No. E-065-2002/0-US-03), with priority to 20 May 2002