DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0456]

Determining Hospital Procedures for Opened-But-Unused, Single-Use Medical Devices; Request for Comments and Information; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 28, 2002 (67 FR 55269). The document announced a request for comments about current practices with respect to opened-but-unused, single-use medical devices. The document was inadvertently published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning, and Legislation (HF–27), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–27, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 02–21891, appearing on page 55269 in the **Federal Register** of Wednesday, August 28, 2002, the following correction is made:

1. On page 55269, in the third column, ''[Docket No. 00D–0053]'' is corrected to read ''[Docket No. 02N–0456]''.

Dated: October 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–27413 Filed 10–28–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0461]

Antimicrobial Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Infectious Diseases Society of America (IDSA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), regarding antimicrobial drug development. The public workshop is intended to provide information for and gain perspective from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of antimicrobial drug development, including the selection of delta in noninferiority (equivalence) clinical trials, the need for newer antimicrobial agents for the treatment of resistant pathogens, and clinical trial design. The input from this public workshop will help in developing topics for further exploration.

Date and Time: The public workshop will be held on November 19 and 20, 2002, from 9 a.m. to 5 p.m.

Location: The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD. Seating is limited and available only on a first-come, first-served basis. Please note there is very limited parking in the vicinity of 5630 Fishers Lane, but it is near the Twinbrook Metro station. Please bring picture identification in order to clear building security.

Contact Person: John H. Powers, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2350, e-mail: powersjoh@cder.fda.gov, or Leo Chan, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2350, e-mail: chanl@cder.fda.gov.

Registration: Preregistration is required. Send registration information (including name, title, firm name, address, telephone, and fax number) to Leo Chan (see the *Contact Person* section of this document) by November 12, 2002. There is no registration fee for the public workshop. Space is limited; therefore, interested parties are encouraged to register early.

Persons needing a sign language interpreter or other special accommodations should notify the contact person at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with IDSA and PhRMA, regarding antimicrobial drug development. On February 19 and 20, 2002, a public meeting of FDA's Anti-Infective Drugs Advisory Committee was held to discuss issues related to the selection of delta in noninferiority (equivalence) clinical trials and the development of antimicrobial agents for the treatment of resistant pathogens (67 FR 3726, January 25, 2002). This public workshop will further expand the discussion of both issues as well as focus on general considerations in designing clinical trials for antimicrobial products. Additional discussion topics include drug development for acute bacterial meningitis, acute exacerbation of chronic bronchitis, and hospital-acquired pneumonia. The input from this public workshop will help in developing topics for further exploration.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Transcripts of the public workshop will be available for review at the Dockets Management Branch Public Reading Room, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and on the Internet at http://www.fda.gov/ohrms/dockets/dockets/dockets.htm or you may request a transcript of the public workshop from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page.

Dated: October 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–27438 Filed 10–28–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA AIDS Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following advisory committee meeting. The meeting is open to the public.

Name: HRSA AIDS Advisory Committee (HAAC).

Date and Time: November 21, 2002; 1:30 p.m.–5 p.m., November 22, 2002; 8:30 a.m.–3:30 p.m.

Place: Radisson Barcelo, 2121 P Street, NW., Washington, DC 20037, Telephone: (202) 293–3100.

Agenda: Agenda items for the meeting include a discussion of the involvement of Community and Migrant Health Centers in HIV care, HIV medical certification, HRSA restructuring, AIDS Drug Assistance Program issues, Native American issues, and HAAC

planning for reauthorization of the CARE Act.

For Further Information Contact: Anyone requiring further information should contact Shelley Gordon, HIV/AIDS Bureau, Parklawn Building, Room 16C–26, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–9684.

Dated: October 17, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–27520 Filed 10–28–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Nucleic acid encoding mesothelin, a differentiation antigen present on mesothelium, mesotheliomas and ovarian cancers'' U.S. Patent 6,152,430, Issued November 28, 2000, and ''Mesothelium antigen and methods and kits for targeting it'' U.S. Patent 6,083,502, Issued July 4, 2000

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1) (i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent 6,153,430: ''Nucleic acid encoding Mesothelin, a differentiation antigen present on mesothelium, mesotheliomas and ovarian cancers'' issued November 28th, 2000, and U.S. Patent 6,083,502: ''Mesothelium antigen and methods and kits for targeting it'' issued July 4th, 2000, to Cell Genesys, Inc., which is located in Foster City, California. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to human gene therapy using peptides or antibody fragments for the treatment of cancer.

DATES: Only written comments and/or license applications that are received by the National Institutes of Health on or before December 30, 2002 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Brenda J. Hefti, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 496–7056, x206; Facsimile: (301) 402–0220; and e-mail: *heftib@od.nih.gov.*

SUPPLEMENTARY INFORMATION: The prospective exclusive license: will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

The technology claimed in the issued patent relates to mesothelin, which is associated with mesotheliomas and ovarian cancers. The invention includes uses for the amino acid and nucleic acid sequences for mesothelin, recombinant cells expressing it, methods for targeting and/or inhibiting the growth of cells bearing mesothelin, methods for detecting the antigen and its expression level as an indication of the presence of tumor cells, and kits for such detection.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 15, 2002.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 02–27517 Filed 10–28–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Modulating IL–13 Activity Using Mutated IL–13 Molecules that are Antagonists or Agonists of IL–13'', PCT Application PCT/US00/31044

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1) (i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in PCT application PCT/US00/31044 , entitled ''Modulating IL–13 Activity Using Mutated IL–13 Molecules that are Antagonists or Agonists of IL–13'', which was filed on November 10, 2000 to NeoPharm, Incorporated which is located in Lake Forest, Illinois. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to therapy for asthma and other immunological disorders.

DATES: Only written comments and/or license applications that are received by the National Institutes of Health on or before December 30, 2002 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Brenda J. Hefti, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 496–7056, x206; Facsimile: (301) 402–0220; and e-mail: heftib@od.nih.gov.

SUPPLEMENTARY INFORMATION: The prospective exclusive license: will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

The technology claimed in the issued patent relates to mutated forms of IL–13, either agonists or antagonists, which have higher binding affinity for the IL–13 receptor than does wild-type IL–13. The application also claims therapeutic uses of these mutated forms of IL–13, and their use as targeting moieties.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.