

1-888-CBER-FAX or 301-827-3844.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma." The draft guidance document outlines FDA's approach to the development and implementation of nucleic acid testing of infectious agents when intended to screen blood donors for manufacturing of blood products. FDA considers nucleic acid testing of plasma pools to be donor screening.

The draft guidance document represents the agency's current thinking regarding nucleic acid testing of pooled plasma for viral detection in blood and blood products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

##### II. Comments

The draft guidance document is being distributed for comment purposes only. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by January 25, 2000, to ensure their adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: November 15, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy,*

[FR Doc. 99-30702 Filed 11-24-99; 8:45 am]

**BILLING CODE 4160-01-F**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Health Care Financing Administration

[Docket Identifier: HCFA-R-0250]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* Skilled Nursing Facility (SNF) Resident Assessment MDS Data and Supporting Regulations in 42 CFR 413.343 and 424.32; *Form No.:* HCFA-R-250 (OMB# 0938-0739); *Use:* Skilled Nursing Facilities (SNFs) are required to submit Resident Assessment Data as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337. Pursuant to sections 4204(b) and 4214(d) of OBRA 1987, the current requirements related to the submission and retention of resident assessment data for the 5th, 30th and 60th days following admission, necessary to

administer the payment rate methodology described in 413.337, is subject to the Paperwork Reduction Act; *Emergency:* Monthly; *Affected Public:* Business or other for-profit, and Not-for-profit; *Number of Respondents:* 17,000; *Total Annual Responses:* 204,000; *Total Annual Hours:* 5,696,218.25.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 16, 1999.

**John Parmigiani,**

*Acting HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 99-30786 Filed 11-24-99; 8:45 am]

**BILLING CODE 4120-03-M**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Institutes of Health

#### Prospective Grant of Exclusive License: "Immunoconjugates Having High Binding Affinity"

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

**ACTION:** Notice.

**SUMMARY:** This notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(I) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to U.S. Patent Applications 09/321,490, entitled: "Immunoconjugates Having High Binding Affinity" and corresponding foreign patent applications to NeoPharm, Inc. having a place of business in Bannockburn, Illinois. The patent rights in these inventions have been assigned to the United States of America and the

contemplated license may be limited to the use of the SS(dsFv)-PE38 immunotoxin and relevant patent applications for the therapeutic treatment of ovarian cancer and mesotheliomas.

**DATES:** Only written comments and/or applications for a license which are received by NIH on or before February 24, 2000 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: J.R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804. Telephone: (301) 496-7735 ext. 206; Facsimile: (301) 402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:** The technology disclosed in USPA 09/321,490 relates to anti-mesothelin antibodies, including Fv molecules, with a particular high affinity for mesothelin, and immunoconjugates employing them. Also, described are DNA sequences plus diagnostic and therapeutic methods using the antibodies. The anti-mesothelin antibodies are well-suited for the diagnosis and treatment of cancers of the ovary, stomach, squamous cells, mesotheliomas, and other malignant cells expressing mesothelin.

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 404.7. The prospective exclusive license may be granted unless within ninety (90) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the use of the SS(dsFv)-PE-38 immunotoxin under the relevant patent applications for the therapeutic treatment of ovarian cancer and mesotheliomas.

Applications for a license [i.e., completed "Application for License to Public Health Service Inventions] in the field of use of the SS(dsFv)-PE38 immunotoxin and the relevant Patent Applications for the therapeutic treatment of ovarian cancer and mesotheliomas filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections will not be

made available for public inspection and, to the extent by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 16, 1999.

**Jack Spiegel,**

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

[FR Doc. 99-30717 Filed 11-24-99; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, December 6, 1999, 8:00 PM to December 8, 1999, 1:00 PM, National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6 Floor, Conference Room 10, Bethesda, MD 20892 which was published in the **Federal Register** on November 16, 1999, 64FR62210-62211.

NCAB will also meet in closed session on December 6, 1999 from 8:30 AM to 4:00 PM.

Dated: November 17, 1999.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Policy, NIH.*

[FR Doc. 99-30712 Filed 11-24-99; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; 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 a meeting of the National Advisory General Medical Sciences Council.

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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or

contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory General Medical Sciences Council.

*Date:* January 27-28, 2000.

*Closed:* January 27, 2000, 8:30 AM to 11:00 AM.

*Agenda:* To review and evaluate grant applications.

*Place:* Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

*Open:* January 27, 2000, 11:00 AM to 6:00 PM.

*Agenda:* For the discussion of program policies and issues, opening remarks, report of the Director, NIGMS, and other business of the Council.

*Place:* Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

*Closed:* January 28, 2000, 8:30 AM to adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

*Contact Person:* W. Sue Shafer, Deputy Director, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 2AN-32C, Bethesda, MD 20892, (301) 594-4499.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 18, 1999.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-30714 Filed 11-24-99; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institutes of Mental Health; Notice of Closed 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 following meeting.