Kent R. Johnson, Center for Drug Evaluation and Research (HFD–550), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2080; or
Jeffrey N. Siegel, Center for Biologics Evaluation and Research (HFM–582), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5094; or
Sahar M. Dawisha, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3091, ext. 196, FAX 301–594–2358.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA).'' The guidance contains recommendations on the timing, design, and conduct of preclinical and clinical trials for RA products and on special considerations for juvenile RA.

This guidance has been under development since 1995. The first version of the guidance was completed in March 1996. An additional section on juvenile RA was added in May of that year. A second version was completed in January 1997. Two public workshops have been held on the topic, on March 27, 1996, and on July 23, 1996. On February 5, 1997, the draft guidance was discussed at a meeting of the Arthritis Advisory Committee. Another draft version, published for comment on March 18, 1998 (63 FR 13259), incorporated suggestions made during the February 5, 1997, Arthritis Advisory Committee. In developing this final version of the guidance, FDA considered comments submitted to the docket on the March 18, 1998, draft guidance.

This guidance represents the agency's current thinking on RA. 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.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3776 Filed 2–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–4008–N]

Medicare Program; Establishment of the Citizens Advisory Panel on Medicare Education and Requests for Nominations for Members

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act (FACA), the Department of Health and Human Services (DHHS) announces the establishment by the Secretary of the Citizens Advisory Panel on Medicare Education (CAP–ME). The Secretary, DHHS, signed the charter establishing the Committee on January 21, 1999. This notice also requests nominations for members for the panel. The Committee shall terminate on January 22, 2001, unless the Secretary, DHHS, formally determines that continuance is in the public interest.

This Committee shall advise and make recommendations to the Secretary, DHHS, and the Administrator of the Health Care Financing Administration (HCFA) on opportunities for HCFA to make more effective use of its National Medicare Education Program and other HCFA programs that help Medicare beneficiaries understand the expanded range of Medicare options available with the passage of the Medicare+Choice program.

DATES: Nominations for members will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on April 5, 1999.

ADDRESSES: You may mail or deliver nominations for membership to the following address: Linda Levin, Center for Beneficiary Services, Health Care Financing Administration, 7500 Security Boulevard, Room S1–08–07, Baltimore, MD 21244-1850.

A request for a copy of the Secretary's charter for the CAP–ME should be submitted to Eric Katz, J.D., Center for Beneficiary Services, Health Care Financing Administration, 7500 Security Boulevard, Room S1–08–07, Baltimore, MD 21244-1850, (410) 786–6477, or by e-mail to ekatz@hcfa.gov.

FOR FURTHER INFORMATION CONTACT: Eric Katz, (410) 786–6477.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

The Citizens Advisory Panel on Medicare Education (CAP–ME) is governed by provisions of Public Law 92–463 as amended (5 U.S.C. Appendix 2), which sets forth standards for the formulation and use of advisory committees. The Secretary, DHHS, has found that the CAP–ME is necessary and in the public interest.

The CAP–ME will consist of 10 appointed members from among authorities in disability and chronic disease interests, minority populations, health consumer interests, seniors' organizations, health communications and policy, research and philanthropic organizations, health insurers and plans, employer groups, and health providers.

The CAP–ME will focus its review on the National Medicare Education Program and our other efforts to help Medicare beneficiaries and those who assist them find accurate and current information about new Medicare options and benefits under the Medicare+Choice program. The committee will also identify best practices in consumer health education that could enhance our efforts to inform and assist Medicare beneficiaries about their health plan options. An annual report to our Administrator will summarize the panel's findings and any recommendations the panel may provide.

We are requesting nominations for voting members to serve on the CAP–ME. We have a special interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the advisory committee and, therefore, encourage nominations of qualified candidates from these groups. We also seek to ensure geographic diversity in the composition of the panel.

All nominations and curricula vitae for the CAP-ME should be sent to Linda Levin at the address in the **ADDRESSES** section of this notice.

II. Criteria for Members

Persons nominated for membership should have expertise in one or more of the following areas: disability and chronic disease interests, minority populations, health consumer interests, seniors' organizations, health

communications and policy, research and philanthropic organizations, health insurers and plans, employer groups, and health providers.

Nominations must state that the nominee is willing to serve as a member of the CAP-ME and appears to have no conflict of interest that would preclude membership. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Members shall be appointed to a term of between 1 and 4 years, with 3- and 4-year appointments contingent on the Secretary deciding it is in the public interest to continue this Committee beyond the initial 2-year term described in the Charter.

Any interested person may nominate one or more qualified persons. Self-nominations will also be accepted.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 5, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99–3557 Filed 2–11–99; 11:31 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

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.

ADDRESSES: Licensing information and a copy of the U.S. patent applications referenced below may be obtained by contacting J.R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone: 301/496–7056 ext. 206; fax: 301/402–0220; e-mail: jd212g@nih.gov). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

Specific Killing of HIV-Infected Lymphocytes by a Recombinant Immunotoxin Directed by a Recombinant Immunotoxin Directed Against the HIV–1 gp120 Envelope Glycoprotein

Drs. Ira H. Pastan (NCI), Tapan K. Bera (NCI), Paul E. Kennedy (NIAID), Edward A. Berger (NIAID), and Carlos F. Barbas III (EM-The Scripps Research Institute)

Serial No. 60/088,860—Filed June 11, 1998

Since the initial isolation of HIV in 1983, and its identification as the causative agent of AIDS, tremendous research efforts have been expanded to understand the cause and pathogenesis of AIDS, but an effective therapy leading to a cure for AIDS has, as of this date, not been successful or accomplished. There are several therapeutic drugs available to treat infected patients that prolong life and somewhat control symptoms.

The major approaches for the treatment of individuals with AIDS or HIV infections are the administration of drugs such as reverse transcriptase inhibitors (e.g., AZT (3′-azido-3′-deoxythymidine) or ddi (2′,3-dideoxyinosine) which act by inhibiting synthesis of proviral genome after the virion has entered the host cell and protease inhibitors which block the production of infectious virions. Although these agents can effectively inhibit HIV spread *in vivo* and *in vitro*, they do not kill those cells that are already infected with the HIV virus. Recently, a highly active antiretroviral therapy (HHAT) shows encouraging results in reducing viral load in lymphoid tissue of HIV infected patients. In this approach a cocktail consisting of an HIV protease inhibitor and two reverse transcriptase inhibitors is administered. However, again, while significant progress has been made recently in the treatment of HIV–1 infection, we are not yet close to a cure for AIDS.

The technology available from NIH is directed to an immunotoxin that specifically binds to and kills cells displaying an HIV gp 120 coat protein. The immunotoxin comprises an anti-gp 120 antibody directed to the conserved CD4 binding site of gp 120 attached to a cytotoxin (e.g., a Pseudomonas exotoxin). In one preferred embodiment the immunotoxin is a recombinantly expressed fusion protein comprising a disultfide linked Fv region attached to a modified Pseudomonas exotoxin [i.e., 3B3 (Fv)–PE38]. The technology is directed to a pharmaceutical composition, to the composition of the immunotoxin, to methods for killing HIV infected cells, and to a kit for killing cells that display a gp 120 protein.

Recombinant Anti-Tumor RNases

Drs. Susanna M. Rybak (FCRDC) and Dianne L. Newton (FCRDC)

Serial No. 60/079,751—Filed March 27, 1998

The above mentioned invention provides for novel recombinant ribonuclease proteins which when expressed by bacteria are active antitumor agents. Additionally the recombinant ribonucleases of this invention can be fused inframe with ligand receptor binding moieties to form specifically cytotoxic fusion proteins. Furthermore, these proteins are more active than ribonucleases currently available. Because these proteins are recombinant proteins, mutations that increase cytotoxicity can be engineered. The present invention discloses the cloning and the sequence of cDNA from the liver of female Rana pipiens that encodes a novel recombinant RNase and describes some of the expressed proteins' unique cytotoxic properties. The novel RNase is a protent cytotoxic agent to various cancer cell lines (e.g.., neoplastic Kaposi's sacrcoma derived endothelial cells) and linked to a ligand, such as anti-CD22 antibody, has been found to be efficacious against human lymphoma cells.

Targeting Antigens to the MHC Class I Processing Pathway With an Anthrax Toxin Fusion Protein

Dr. Kurt R. Klimpel (NIDCR), Theresa J. Goletz (NCI), Naveen Arora (NIDCR), Stephen H. Leppla (NIDCR), and Jay A. Berzofsky (NCI)

DHHS Ref. No. E–171–96/0—Filed September 17, 1996; Serial No. 08/937,276—Filed September 15, 1997

The mammalian immune system reacts to invading pathogens by mounting two broad defenses: the cell-mediated response and the humoral response. Viral and other intracellular infections are controlled primarily by the cell-mediated immune system. This control is achieved through recognition of foreign antigen displayed on the cell surface of an infected cell. The objective for a vaccine that stimulates the cell-mediated immune system is to deliver protein antigens to the cell cytosol for processing and subsequent presentation by MHC class I molecules. The present