Health Care Financing Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the 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.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Evaluation of the Per-Episode Home Health Prospective Payment Demonstration; *Form No.:* HCFA–R–195; *Use:* This evaluation will collect primary data from samples of patients and from demonstration agencies to assess impacts of per-episode payment on access to care, quality of care, and the use of non-Medicare services; *Frequency:* Other (one time); *Affected Public:* Not for profit institutions, individuals and households, business or other for profit; *Number of Respondents:* 19,191; *Total Annual Hours:* 1,901.

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* ICR in the Hospice Care Regulation for 42 CFR@418.22, 418.24, 418.28, 418.56(b), 418.56(e)(1), 418.56(e)(3), 418.58, 418.70(d), 418.70(e), 418.74, 418.83, 418.96(b) and 418.100(b); *Form No.:* HCFA–R–30; *Use:* The HCFA-R–30 establishes standards for hospices who wish to participate in the Medicare program. The regulations establish standards for eligibility, reimbursement standards and procedures, and delineate conditions that hospices must meet to be approved for participation in Medicare. *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,927; *Total Annual Responses:* 1,927; *Total Annual Hours Requested:* 3,977,762.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Blood Bank Inspection Checklist and Report; *Form No.:* HCFA–282; *Use:* The blood bank inspection checklist instrument is used by State agency to record data collected as part of the survey and certification process to determine compliance with the requirement for blood bank services under Clinical Laboratory Improvement Amendments; *Frequency:* Biennially; *Affected Public:* State, local, and tribal government, business or other for profit, not for profit institutions, federal government; *Number of Respondents:* 2,500; *Total Annual Hours:* 1,250.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 2, 1996.

Edwin J. Glatzel,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–20235 Filed 8–7–96; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: HIV Protease-Related Technologies

AGENCY: National Institutes of Health.

ACTION: Notice.

The inventions referenced 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 U.S. companies and may also be available for licensing.

ADDRESS: Licensing information and a copy of the patent applications and issued patents may be obtained by contacting Cindy K. Fuchs, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7735 ext 232; fax 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Human Immunodeficiency Virus Specific Proteolytic Enzyme and a Method for Its Synthesis and Renaturation

S Oroszlan, TD Copeland (NCI)

Serial No. 07/057,183 filed 01 Jun 87

U.S. Patent No. 5,252,477 issued 12 Oct 93

Inhibition of the HIV protease enzyme is currently an important component of combination therapies for HIV infection and AIDS. This patent discloses the amino acid and DNA sequences for natural and biologically active synthetic HIV–1 protease, as well as a method for its synthesis and purification. The synthetic enzyme, which has the correct stereospecific conformation, can be used to design HIV–1 protease inhibitors and to test their effectiveness against HIV–1. This technology is described further in the following publications: Copeland, T.D., et al., *Gene Anal Techn* 5: 109–115 (1988) and Louis, J.M., et al., *Biochem Biophys Res Comm* 164(1): 30–38 (1989). (Portfolio: Infectious Diseases—Reagents)

Human Immunodeficiency Virus Specific Proteolytic Enzyme and a Method for Its Synthesis and Renaturation

S Oroszlan, TD Copeland (NCI)

Serial No. 08/100,703 filed 30 Jul 1993

U.S. Patent No. 5,354,683 issued 11 Oct 94 (CIP of U.S. Patent 5,252,477)

Inhibition of the HIV protease enzyme is currently an important component of combination therapies for HIV infection and AIDS. This patent discloses the amino acid sequence of natural and biologically active synthetic HIV–2 protease, as well as a method for its synthesis and purification. The synthetic enzyme, which has the correct stereospecific conformation, can be used to design HIV–2 protease inhibitors and to test their effectiveness against HIV–2. This technology is described further in Copeland, T.D., et al., *Gene Anal Techn* 5: 109–115 (1988). (Portfolio: Infectious Diseases—Reagents)

Synthetic HIV Protease Gene and Method for Its Expression

JL Medabalimi (NIDDK), S. Oroszlan, PT Mona (NCI)

Filed 02 Mar 93

Serial No. 08/024,916 (CIP of U.S. Patent 5,252,477)

Inhibition of the HIV protease enzyme is currently an important component of combination therapies for HIV infection and AIDS. This patent application discloses a DNA construct for biologically active recombinant HIV–1 protease, as well as a method for its production and purification. The recombinant enzyme can be used to design HIV–1 protease inhibitors and to test their effectiveness against HIV–1. This technology is described further in Louis, J.M., et al., *Biochem Biophys Res Comm* 159(1): 87–94 (1989). Foreign intellectual property rights are available in Australia, Canada, Israel, and Japan. (Portfolio: Infectious Diseases—Reagents)

Transframe Peptide Inhibitor of Viral Protease

JL Medabalimi (NIDDK)

Filed 05 Oct 95

Serial No. 08/539,432

The inhibition of protease is an increasingly important approach in the control of pathogenic organisms, including retroviruses such as the human immunodeficiency virus (HIV). The present invention embodies small, water-soluble peptides isolated from a native retroviral inhibitory sequence that block maturation of HIV protease and also inhibit the mature enzyme. The peptides may be used in the treatment of HIV-infected cells, in the preparation of HIV vaccine formulations, in the generation of clinically relevant anti-HIV antibodies and anti-idiotypic antibodies, and as components of a screening assay or kit used to identify other similarly acting HIV protease inhibitors. The invention encompasses the inhibitory peptides, pharmaceutical compositions containing the peptides, methods of using the peptides in the treatment and prevention of HIV-induced pathogenesis, a kit and methods for screening test compounds (peptide or non-peptide) for use as HIV protease inhibitors, and antibodies and anti-idiotype antibodies to HIV protease. (Portfolio: Infectious Diseases—Therapeutics, anti-virals, AIDS; Infectious Diseases—Vaccines, viral, AIDS; Infectious Diseases—Reagents)

2,5-Diamino-3,4-Disubstituted-1,6-Diphenylhexane Isosteres Comprising Benzamide, Sulfonamide and Anthranilimide Subunits and Methods of Using Same

RS Randad, JW Erickson (NCI)
Filed 20 Dec 94
Serial No. 08/359,612

This invention concerns retroviral protease inhibitors which are potential drugs for the treatment of HIV infection and AIDS. The compounds of the invention contain novel nonpeptidic and achiral substituents, wherein achiral benzamide, sulfonamide and anthranilamide subunits are introduced onto the 2,5-diamino-3,4-disubstituted-1,6-diphenylhexane isostere core. The compounds are resistant to viral and mamalian protease degradation. The best compounds had a K_i (inhibition constant) of less than 100 pM for HIV protease. CEM cells chronically infected with HIV–1 were used to test the *in vitro* anti-retroviral activity of the compounds. The concentrations needed to inhibit 50% of viral activity were on the order of 5 nM. Therefore, these compounds compare favorably in their anti-retorviral potency to HIV protease inhibitors currently in clinical trials and on the market. These compounds are described in three recent publications: Randad, R.S., et al., *Bioorganic & Medicinal Chemistry Letters*, 5(15): 1707–1712 (1995); Randad, R.S., et al., *Bioorganic & Medicinal Chemistry Letters*, 5(21): 2557–2562 (1995); and Randad, R.S., et al., *Bioorganic & Medicinal Chemistry Letters* (1996, in press). Foreign intellectual property rights are available in PCT member countries. (Portfolio: Infectious Diseases—Therapeutics, anti-virals, AIDS)

Novel Retroviral Agents Containing Anthranilamide, Substituted Benzamide and Other Subunits, and Methods of Using Same

RS Randad, JW Erickson, TN Bhat (NCI)
Filed 22 Nov 95
Serial No. 08/562,013

This invention concerns retroviral protease inhibitors which are potential drugs for the treatment of HIV infection and AIDS. The compounds of the invention are symmetric and asymmetric 2,5-diamino-3,4-disubstituted-1,6-diphenylhexane (DAD) isosteres with achiral, nonpeptidic anthranilimide, substituted benzamide, sulfonamide and other subunits. The DAD isosteres may also include amino acid subunits. The compounds are more resistant to mammalian and viral protease degradation than currently available retroviral protease inhibitors, and therefore, have greater plasma half-life and oral bioavailability. Pharmacokinetic and bioavailability studies are currently being conducted. The best compound has a K_i (inhibition constant) of approximately 3 pM for HIV protease. *In vitro* anti-retroviral activity was tested in CEM cells chronically infected with HIV–1. The concentration required to inhibit 50% of viral activity was on the order of 6 nM. This compound thus compares favorably in its *in vitro* anti-retroviral potency to HIV protease inhibitors currently in clinical trials and on the market. (Portfolio: Infectious Diseases—Therapeutics, anti-virals, AIDS)

Dated: July 30, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 96–20266 Filed 8–7–96; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

The inventions listed below are owned by agencies 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 U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications and issued patents listed below may be obtained by contacting David Sadowski at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone: 301/496–7056 ext 288; fax: 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Nurse's Hand Protection

B Thornton, A Peterson, M Allen, B Fahey, M Woolery Antill, J Taylor, V Wheeler, P Coleman, S Kedrowski, L Jeanneret (CC)
Filed 15 Aug 95
Serial No. 08/515,499

This invention provides nurses and other health care workers with protection against accidental needle sticks. Specifically, a device has been