for the treatment of patients with locally advanced metastatic non-small cell lung cancer after prior chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALIMTA (U.S. Patent No. 5,344,932) from Eli Lilly and Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 31, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ALIMTA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ALIMTA is 4,166 days. Of this time, 4,038 days occurred during the testing phase of the regulatory review period, while 128 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: September 10, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 10, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 30, 2003. The applicant claims September 29, 2003, as the date the new drug application (NDA) for ALIMTA (NDA 21–462) was initially submitted. However, FDA records indicate that NDA 21–462 was submitted on September 30, 2003.

3. *The date the application was approved*: February 4, 2004. FDA has verified the applicant's claim that NDA 21–462 was approved on February 4, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,784 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may, submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination by April 10, 2006, Furthermore, any interested person may petition FDA, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 7, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–1642 Filed 2–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Intramural Research, Training Program Application

Summary: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NIH Intramural Research Training Program Applications.

Type of Information Collection Request: Revision/OMB No. 0925–0299; February 28, 2006.

Need and Use of Information Collection: The proposed information collection activity is for the purpose of collecting data related to the availability of Training Fellowships in the NIH Intramural Research Program. This information must be submitted in order to receive due consideration for a fellowship and will be used to determine the eligibility and quality of potential awardees.

Frequency of Response: On occasion.

Affected Public: Individuals seeking Intramural Training Opportunities and references for these individuals.

Type of Respondents: Postdoctoral, predoctoral, post-baccalaureate, technical, clinical, and student IRTA applicants. There are no capital costs, operating costs, and/or maintenance costs to report.

Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Postdoctoral	1,000	3.00	1.00	3,000
Predoctoral	175	1.00	1.00	175
Postbaccalaureate	2,090	1.00	1.00	2,090
Technical	175	1.00	1.00	175
Clinical	300	1.00	1.00	300
Student	7,000	1.00	1.00	7,000
References for all categories	31,395	1.00	0.33	10,360
Total	42,135	1.0474665	0.5482378	23,100

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Steve Alves, Web site Programs Specialist, Office of Intramural Training and Education, OD, NIH, Building 2, Room 2W17, 2 Center Drive MSC 0240, Bethesda, MD 20892–0240, or call non-toll-free number (301) 402–1294, or e-mail your request, including your address to: *alvess@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 23, 2006.

Christine Major,

Acting Director, Office of Human Resources, National Institutes of Health.

[FR Doc. 06–1140 Filed 2–7–06; 8:45 am]

BILLING CODE 4140–01–M

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.

Oligodeoxyribonucleotides Comprising O^{6}6-Benzylguanine and Their Use

Robert C. Moschel *et al.* (NCI)
U.S. Patent No. 6,060,458 issued 09 May 2000 (HHS Reference No. E–104–1998/0–US–01).
Licensing Contact: George G. Pipia, PhD.; 301/435–5560; *pipiag@mail.nih.gov.*

Chemotherapy is a common treatment for a variety of cancers. Chemotherapeutic alkylating agents represent a key category of commonly used antineoplastic drugs. These drugs are active against chronic leukemias, non-Hodgkin lymphoma, Hodgkin disease, multiple myeloma, lung, breast, ovarian cancer, and certain other cancers. The DNA repair protein, O^6-alkylguanine-DNA alkyltransferase (AGT), is a primary source of tumor cell resistance to the alkylating drugs that alkylate the O^6 position of guanine in DNA. AGT therefore becomes the prime target for modulation. Currently, AGT inactivators are used as adjuvants to enhance chemotherapy by the alkylating drugs.

O^6-Benzylguanine is the prototype AGT inactivator in phase I, II and III clinical trials as an adjuvant to improve chemotherapy. Although O^6-benzylguanine is a promising AGT inactivator, it is not an ideal drug. O^6-Benzylguanine is only sparingly soluble in water, and it is not effective in inactivating some mutant alkyltransferase proteins that could possibly be produced after repeated chemotherapy cycles. The present invention describes oligodeoxyribonucleotides containing O^6-benzylguanine residues as another class of AGT inactivators, and discusses the advantages of their use in comparison to O^6-benzylguanine as the free base. Oligodeoxyribonucleotides containing O^6-benzylguanine residues are extremely water soluble and can efficiently inactivate AGT at much lower concentrations than O^6-benzylguanine. In addition, they are effective in inactivating several mutant alkyltransferase proteins that are highly resistant to inactivation by O^6-benzylguanine. Furthermore, positioning O^6-benzylguanine near the 3′-or 5′-terminus of these oligodeoxyribonucleotides improves their resistance to degradation by cellular nuclease proteins. Therefore, oligodeoxyribonucleotides containing multiple O^6-benzylguanine residues may be more effective chemotherapy adjuvants than O^6-benzylguanine.

The CCHC Zinc Fingers of the Retroviral Nucleocapsid Protein Comprises a New Target Useful in Identification and Evaluation of Anti-HIV Therapeutics

Louis E. Henderson *et al.* (NCI)
U.S. Patent No. 6,001,555 issued 14 Dec 1999 (HHS Reference No. E–174–1993/1–US–01).
Licensing Contact: Sally H. Hu, PhD., M.B.A.; 301/435–5606; *hus@mail.nih.gov.*

According to a recently released report from the WHO, an estimated 40.3 million people worldwide are currently living with HIV infection, and more than three million people died of AIDS-related illnesses in 2005. In response to increased prevalence of HIV/AIDS, the search for effective antiretroviral therapy is intensive. The present invention describes compounds that may be useful for developing new types of antiretroviral therapeutics for HIV infection.

HIV–1 contains domains known as ''CCHC zinc fingers'' in the retroviral nucleocapsid (NC) protein. Nucleocapsid CCHC zinc fingers are highly conserved throughout nearly all retroviruses. They are sequences of 14 amino acids with four invariant residues, $Cys(X)_2Cys(X)_4His(X)_4Cys$, which chelate zinc and perform essential functions in viral infectivity. HIV–1 NC has two CCHC zinc fingers, both of which are necessary for infectivity. Many compounds that disrupt the CCHC zinc fingers also inactivate HIV–1 by preventing the initiation of reverse transcription and by blocking production of infectious virus from previously infected cells. Compounds with this activity may be useful for developing new types of antiretroviral drugs. In addition, compounds with this activity can be useful for production of chemically inactivated retroviral particles that lack infectivity but retain structurally and functionally intact envelope glycoproteins. Such inactivated particles may be useful both as in vitro reagents in a variety of applications and as immunogens for whole inactivated virus vaccines.

The present invention concerns antiretroviral compounds that disrupt the CCHC zinc fingers and assays for identifying such compounds. The invariant nature of retroviral zinc fingers also extends the usefulness of these compounds to other retroviruses. Thus these assays are also useful for screening compounds effective against