DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–287, HCFA–1491, HCFA–P–15A & HCFA–37]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal 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:* Extension of a currently approved collection;

Title of Information Collection: Home Office Cost Statement and Supporting Regulations in 42 CFR Section 413.17;

Form No.: HCFA–287 (OMB #0938–0202);

Use: Medicare law permits components of chain organizations to be reimbursed for certain costs incurred by the Home Offices of the chain. The Home Office Cost Statement is required by the fiscal intermediary to verify Home Office Costs claimed by the components. This requires that the provider include in its costs, the costs incurred by the related organization in furnishing such services, supplies or facilities.

Frequency: Annually.

Affected Public: Not-for-profit institutions, Business or other for-profit.

Number of Respondents: 1,231.

Total Annual Responses: 1,231.

Total Annual Hours: 573,646.

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

Title of Information Collection: Request for Medicare Payment—Ambulance and Supporting Regulations in 42 CFR Section 410.40 and 424.124;

Form No.: HCFA–1491 (OMB #0938–0042);

Use: This form is used by physicians, suppliers, and beneficiaries to request payment of Part B Medicare services. It is used to apply for reimbursement for ambulance services.

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or households, and Not-for-profit Institutions;

Number of Respondents: 9,634,435;

Total Annual Responses: 9,634,435;

Total Annual Hours: 406.251.

(3) *Type of Information Collection Request:* New Collection;

Title of Information Collection: Medicare Information Needs: Supplement to the Medicare Current Beneficiary Survey (MCBS).

Form No.: HCFA–P–15A (OMB# 0938–NEW);

Use: This supplement to the MCBS builds upon the previously fielded Round 18 Supplement, which provided useful information to HCFA's Center for Beneficiary Services on beneficiary information needs and preferences for how to receive information. Results from this data collection will be used by HCFA to guide continued development of communication and education programs for Medicare beneficiaries.

Affected Public: Individuals or Households;

Number of Respondents: 12,000;

Total Annual Responses: 12,000;

Total Annual Hours: 3,000.

(4) *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Medicaid Program Budget Reports and Supporting Regulations in 42 CFR Section 430.30;

Form No.: HCFA–37 (OMB# 0938–0101);

Use: The Medicaid Program Budget report is prepared by the State Medicaid Agencies and is used by HCFA for; (1) developing National Medicaid Budget estimates, (2) quantifying Budget Assumptions, (3) issuing quarterly Medicaid Grant Awards, and (4) collecting projected State receipts of donations and taxes;

Frequency: Quarterly;

Affected Public: State, Local or Tribal Government;

Number of Respondents: 57;

Total Annual Responses: 228;

Total Annual Hours: 7,980.

To obtain copies of the supporting statement 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 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 must be mailed 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: February 22, 1999.

John P. Burke III,

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

[FR Doc. 99–4703 Filed 2–24–99; 8:45 am]

BILLING CODE 4120–03–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 invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESS: Licensing information and a copy of the U.S. patent application 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.

Entitled: Recombinant Ribonuclease Proteins

Inventors: Drs. Susan M. Rybak (NCI–FCRDC), Dianne L. Newton (NCI–FCRDC), and Lluis Boque (EM), Serial No. 08/875,811 filed 2 February 1997, [= PCT/US97/02588 filed 19 February 1997].

This invention describes and relates to the expression of recombinant ribonucleases which are modifications of the native RNase derived from the oocytes of *Rana pipiens.* Various humanized and recombinant forms of these recombinant ribonucleases are described as well as their use as

cytotoxic reagents to inhibit the growth of tumor cells. This invention also describes that when these ribonucleases are expressed recombinantly they have significant increased eytotoxicity. These ribonucleases may be used to form chemical conjugates, as well as form targeted recombinant immunofusion molecules that can be used to decrease tumor cell growth. Importantly, these ribonucleases can be administered directly to patients to decrease and inhibit tumor cell growth without the use of a targeting agent. Humanized versions of these ribonucleases are described with portions of mammalian or human-derived neurotoxin, grafted to the molecule. This invention also includes methods of selectively killing cancer cells using the recombinantly expressed ribonucleases joined to a ligand to create a selective cytotoxic reagent. The method comprises contacting the cells to be killed with a cytotoxic reagent having a ligand binding moiety that specifically delivers the reagent to the cells to be killed. This method may be used for cell separation *in vitro* by selectively killing unwanted types of cells, for example, in bone marrow prior to transplantation into a patient undergoing marrow ablation by radiation, or for killing leukemia cells or T–Cells that would cause graft-versus-host disease.

The above mentioned invention is available, including any available foreign intellectual property rights, for licensing on an exclusive or non-exclusive or non-exclusive basis.

Dated: February 16, 1999.

Jack Spiegel,

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

[FR Doc. 99–4656 Filed 2–24–99; 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, DHHS.

ACTION: Notice

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Entitled: Immunotoxins Directed Against Malignant B-Cells [Immunotoxins, Comprising an ONC Protein, Directed Against Malignant Cells]

Inventors: Drs. Susanna M. Rybak (NCI–FCRDC), Dianne Newton (NCI–FCRDC), and David Goldenberg (EM), DHHS Ref. No. E–157–97/0 filed 2 March 1997, [= PCT/US98/08983 filed 1 May 1998] and 09/071,672 filed 5 May 1998.

This invention relates to immunotoxins, that are useful for killing malignant B-Cells and other malignant cells and are directed to a surface marker on B-Cells and the nucleic acid constructs encoding the immunotoxins. These reagents comprise a toxic moiety that is derived from a *Rana pipiens* protein having a ribonucleolytic activity linked to an antibody capable of specific binding with a chosen tumor cell. It has been found that these immunotoxins are up to 2,000 fold more active against malignant B-Cells than their human RNase counterparts or the toxin itself. These immunotoxins when administered *in vivo* against disseminated tumors, resulted in dramatically lower side effects. These highly effective, but apparently non-toxic immunotoxins directed against such ubiquitous diseases as B-Cell Lymphomas and Leukemias and other malignancies, such as neuroblastoma, present a new and exciting therapeutic option for patients suffering from such diseases.

The above mentioned invention is available, including any foreign intellectual property rights, for licensing on an exclusive or non-exclusive basis.

Dated: February 16, 1999.

Jack Spiegel,

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

[FR Doc. 99–4657 Filed 2–24–99; 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, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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.

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Entitled: Methods for Determining the Prognosis of Breast Cancer Using Antibodies Specific for Thymidylate Synthase

Inventors: Drs. Patrick G. Johnston (NCI) and Carmen J. Allegra (NCI), Serial No. 09/152,647 filed 14 September 1998.

Thymidylate synthase provides the sole de novo source of thymidylate for DNA synthesis. It is also a critical therapeutic target for the fluoropyrimidine cytotoxic drugs, such as fluorouracil (''5-FU'') and flurodeoxyureidine (''FudR''). In pre-clinical and clinical studies increased expression of thymidylate synthase protein has been associated with resistance to 5-FU. The quantitation of thymidylate synthase has traditionally been performed using enzymatic biochemical assays; however, these assays have major limitations when applied to human tumor tissue samples. Recently, monoclonal antibodies have been developed to human thymidylate synthase that have the required sensitivity and specificity to detect and quantitate thymidylate synthase enzyme in formalin-fixed tissue sections. Hence, this invention provides a method for determining the prognosis of a patient afflicted with breast cancer, by obtaining a solid breast tumor tissue sample, measuring the level of thymidylate synthase expression in the