

Annual Burden Hours Requested: 57.61. The annualized cost to respondents is estimated at: \$1,152.30. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the 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: To request more information on the proposed project or obtain a copy of the data collection plans and instruments, contact Ms. Kristie Dionne, Program Analyst, Office of Liaison Activities, NCI, NIH, Building 31, Room 10A06, 9000 Rockville Pike, Bethesda, MD 20892-2580, or call non-toll-free number (301) 594-3194 or e-mail your request, including your address, to liaison@od.nci.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: July 2, 1999.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 17927 Filed 7-13-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Impact and Costs of Sealants in Young Child Population

SUMMARY: Under the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 31, 1999, page 15367, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: The Impact and Costs of Sealants in Young Child Populations.

Type of Information Collection Request: Revision. Need and use of Information Collection; This study will assess the value (costs and effects) of providing dental sealants to the child population with erupted permanent posterior teeth (approximately ages 6-12) under alternative financial support programs in existing oral health care delivery systems and across two socioeconomic groups. The primary objectives of the study are to determine if various levels of dental insurance influence the use of dental sealants, if costs attributable to sealants in a payment program provide value in

terms of reduced caries, and if providing dental sealants to specific tooth surfaces of children merits the investment of limited resources within a larger oral health care program. The findings will provide valuable information concerning: 1. Real disease reductions possible using dental sealants for age-appropriate child populations within the existing oral health delivery system, 2. the costs of, and estimated savings from, providing sealants rather than restorative care, and 3. the marginal benefits and cost benefits of adding sealants to "normative" caries prevention efforts in age-appropriate child populations.

Frequency of Response: On occasion. Affected Public: Individuals or Households, Businesses or other For-Profits. Type of respondents: Children, Parents, and Dentists. Estimated Number of Respondents: 1,200. Estimated Number of Responses per Respondent: 1. Average Burden hours per Response: .1200; and Estimated Total Annual Hours Requested: 766. The annualized cost to respondents is estimated at: \$964. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The number of required respondents has been reduced significantly due to the proposed modification of the approach to meeting the objectives of the study. Data gathered from approximately 400 children enrolled to date under the study's insurance coverage will be supplemented by administrative data already collected from large numbers of children who are receiving dental care through private insurance, the Children's Health Insurance Program, and Medicaid. No contact with these children is required, and there will be no identifying information in the data obtained. The result of the proposed modification is that the respondent burden for the component of this study that involves direct contact with subjects is reduced substantially. The burden estimates are as follows:

	No. of respondents	No. of responses per respondent	Avg. burden/response (hour)
Parents	500	4	.125
Children	400	4	.129
Dentists	300	1	.033

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 function of the agency, including whether the information will have practical utility; (2) the accuracy of the

agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and

clarity of the 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.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Robert H. Selwitz, Health Policy Analysis and Development Branch, NIDCR, NIH, Natcher Building, Room 3AN-44J, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 594-3977, or e-mail your request, including your address to: Robert.Selwitz@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before August 13, 1999.

Dated: July 7, 1999.

Yvonne H. du Buy,
Executive Officer, NIDCR.

[FR Doc. 99-17926 Filed 7-13-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: "Immunotoxin Containing a Disulfide-Stabilized Antibody Fragment Joined to a Pseudomonas Exotoxin that does not Require Proteolytic Activation"

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.

ADDRESSES: 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.

SUPPLEMENTARY INFORMATION:

Invention Title: "Immunotoxin Containing a Disulfide-Stabilized Antibody Fragment Joined to a Pseudomonas Exotoxin that does not Require Proteolytic Activation"

Inventors: Drs. Ira H. Pastan (NCI), and Chin-Tsun Kuan (NCI)

DHHS Ref. No. E-163-93/1 & 2 & 3—USPA SN: 08/809,668—Filed August 21, 1997, [=60/005,388—Filed: October 13, 1995, & PCT/US96/16327/WO 97/13529—Filed: October 11, 1996]

Licensing Contract: J.R. Dixon, Ph.D., (301)-496-7056 Ext. 206; E-Mail: jd212g@NIH.GOV

Immunotoxins were initially produced by chemically coupling antibodies to toxins to form chimeric molecules. In these molecules, the antibody portion mediates selective binding to target cells, while the toxin portion mediates translocation into the cytosol and subsequent cell killing. Several toxins have been used to make immunotoxins including ricin A chain, blocked ricin, saporin, pokeweed antiviral protein, diphtheria toxin, and Pseudomonas Exotoxin ("PE").

The technology disclosed in the above mentioned patent application relates to the production and use of Pseudomonas-derived immunotoxins modified to increase their toxicity and potency and therapeutic agents. In particular, the immunotoxins of this invention includes a disulfide-stabilized ("ds") target-binding agent, such as the variable region of an antibody molecule, and a Pseudomonas Exotoxin that does not require proteolytic activation for cytotoxic activity. Specifically, the invention provides for immunotoxins comprising a Pseudomonas Exotoxin that does not require proteolytic activation for cytotoxic activity attached to an Fv antibody fragment having a variable heavy chain region bound through at least one disulfide bond to a variable light chain region. The combination of a "disulfide-stabilized" binding agent fused to a PE that does not require proteolytic activation and provides an immunotoxin having surprising cytotoxic activity.

The above mentioned Invention is available, including any available

foreign intellectual property rights, for licensing.

Dated: July 2, 1999.

Jack Spiegel,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 99-17928 Filed 7-13-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: "Methods for Predicting the Efficacy of a Chemotherapeutic Regimen for Gastrointestinal Cancers Using Antibodies Specific for Thymidylate Synthase"

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.

ADDRESSES: 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.

SUPPLEMENTARY INFORMATION:

Invention Title: "Methods for Predicting the Efficacy of a Chemotherapeutic Regimen for Gastrointestinal Cancers using Antibodies specific for Thymidylate Synthase"

Inventors: Drs. Patrick G. Johnson (NCI), Edwin R. Fisher (NCI) and Carmen J. Allegra (NCI)

DHHS Ref. No. E-194-95/1 USPA SN: 08/758,034 [= 60/007,825—Filed: December 1, 1995] Filed: November 27, 1996 [E-194-95/1].

Gastric adenocarcinoma is characterized by an extremely virulent behavior and for which mortality approximates the incidence. The vast majority of patients with gastric cancer are diagnosed with advanced stage disease and even after "curative"