(NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This generic clearance request is for the collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. Approval is requested for up to 4 surveys of audiences targeted by the National Diabetes Education Program including people at risk for diabetes, people with diabetes and their families, health care providers, payers and purchasers of health care and health care system policy makers.

Frequency of Response: On occasion. *Affected Public:* Individuals or households; businesses or other for-profit organizations; not-for-profit institutions; Federal government; and State, local or tribal government. *Type of Respondents:* Adults. The annual reporting burden is as follows:

Estimated Number of Respondents: 2200, *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .25; and *Estimated Total Annual Burden Hours Requested:* 200. The annualized cost to respondents is estimated at $5,437.50. There are not Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Total hour burden
Patients and their family members	1000	1	.25	250
People at risk for diabetes	600	1	.25	150
Physicians or other health care providers	600	1	.25	150
Heath care systems	200	1	.25	50
Totals	2,200	.....	.....	600

COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Hourly wage rate	Respondent cost
Patients and their family members	1000	1	$20.00	$5,000.00
People at risk for diabetes	600	1	20.00	3,000.00
Physicians or other health care providers	600	1	75.00	11,250.00
Health care system	200	1	50	2,500.00
Total	.....	.....	.....	$21,750.00

(**Note:** On an annual basis, the average number of respondents is 800; the average number of hours is 200 and the average annual respondent cost is $5,437.50)

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 aassumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimze 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, DC 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 Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, NIDDK, NIH, Building 31, Room 9A04, 31 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301–494–6110 or E-mail your request, including your address to: *Joanne—Gallivan@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 26, 2004.

Barbara Merchant,

Executive Officer, NIDDK, National Institutes of Health.

[FR Doc. 04–5298 Filed 3–8–04; 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 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 contacting Brenda Hefti, Ph.D., Technology Licensing Specialist, Office

of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/435–4632; fax: 301/402–0220; e-mail: *heftib@mail.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

LMB–2, An Immunotoxin That Shows Efficacy in Phase I Clinical Trials in Treating Patients With Chemotherapy-Resistant Hairy Cell Leukemia and Other Hematologic Malignancies

A number of patents and patent applications cover this technology, including but not limited to:

''Reduction of the nonspecific animal toxicity of immunotoxins by mutating the framework regions of the Fv to lower the isoelectric point,'' PCT/US01/43602, by Pastan, Onda, Nagata, Tsutsumi, Vincent, Kreitman, Vasmatzis, and Lee. (DHHS Ref. E–146–1999/0); and

''Recombinant antibody-toxin fusion protein,'' PCT/US90/02097, U.S. Patents 6,051,405, 5.863,745, and 5,696,237, by Fitzgerald, Chaudhary, Pastan, and Waldmann. (DHHS Ref. E–135–1989/0)

The invention provides a recombinant immunotoxin, LMB–2 [anti-Tac(Fv)–PE38], that has been used in Phase I trials to treat hematologic malignancies. The antibody portion of the immunotoxin is an Fv fragment (antigen-binding fragment) of the anti-Tac antibody, and it is fused to truncated Pseudomonas Exotoxin (PE38). This immunotoxin has been used in a Phase I clinical trial (Kreitman *et al.*, 2000; J Clin Oncol 18:1622–1636). Thirty five (35) patients with CD25-expressing hematologic malignancies, for whom standard and salvage therapies failed, were treated with LMB–2. All four patients with hairy cell leukemia (HCL) responded to treatment, and one patient achieved a complete remission that lasted for more than 20 months. Seven partial responses were observed; including responses in patients with cutaneous T-cell lymphoma (one patient), HCL (three patients), chronic lymphocytic leukemia (one patient), Hodgkin's disease (one patient), and adult T-cell leukemia (one patient). Responding patients had 2- to 5-log reductions of circulating malignant cells, improvement in skin lesions, and regression of lymphomatous masses and splenomegaly.

Several improvements on the original immunotoxin have been made (and are also the subject of patents and patent applications). One is the replacement of the single chain Fv with a more stable disulfide stabilized Fv. Another is recombinant immunotoxins that have been modified from a parental immunotoxin to lower liver toxicity. Still another discloses a polyethylene glycol modified form that is less immunogenic and has a longer half life in animals.

BL22, An Immunotoxin That Shows Efficacy in Clinical Trials in Treating Patients With Chemotherapy-Resistant Hairy Cell Leukemia, and Ha22, a Newly Engineered Immunotoxin, Which Shows Improved Cytotoxic Activity Over BL22

A number of patents and patent applications cover this technology, including but not limited to:

''Reduction of the nonspecific animal toxicity of immunotoxins by mutating the framework regions of the Fv to lower the isoelectric point,'' PCT/US01/43602, by Pastan, Onda, Nagata, Tsutsumi, Vincent, Kreitman, Vasmatzis, and Lee. (DHHS Ref. E–146–1999/0);

''Immunotoxin containing a disulfide-stabilized antibody fragment joined to a Pseudomonas Exotoxin that does not require proteolytic activation,'' PCT/US94/06678, by Pastan and Kuan. (DHHS Ref. E–163–1993/0,1);

''Recombinant antibody-toxin fusion protein,'' PCT/US90/02097, U.S. Patents 6,051,405, 5.863,745, and 5,696,237, by Fitzgerald, Foudhary, Pastan, and Waldmann. (DHHS Ref. E–135–1989/0); and

''PEGylation of linkers improves antitumor activity and decreases toxicity of immunoconjugates,'' PCTUS01/18503, by Pastan, Tsutsumi, Onda, Nagata, Lee and Kreitman. (DHHS Ref. E–216–2000/2)

The invention provides recombinant immunotoxins one of which has been used in a clinical trial to treat hematologic malignancies. The antibody portion of the parental immunotoxin is an anti-CD22 RFB4(dsFv) antibody or antigen-binding fragment, and it is fused to truncated Pseudomonas Exotoxin (PE38), creating the BL22 immunotoxin.

BL22 has been used in a phase I clinical trial for CD22 expressing malignancies and a high complete response rate observed in refractory Hairy Cell Leukemia (HCL). Of 16 cladribine-resistant patients, 11 had a complete remission and 2 had a partial remission with BL22 (Kreitman *et al.*, N Engl J Med. 2001 Jul 26;345(4):241–7). Further responses have been observed since this publication and a phase 2 trial in HCL has just opened. Phase 2 trials in CLL and pediatric ALL should open soon.

HA22 is an improved form of BL22 with mutations in the antibody portion that increase its binding affinity for CD22 and its ability to kill cells from patients with low CD22 expression as occurs in CLL.

Several improvements on the original immunotoxin are also disclosed in these patents and patent applications. One of these is an application disclosing recombinant immunotoxins that have been modified from a parental immunotoxin to lower liver toxicity. Another generally discloses several different immunotoxins that might prove useful in treating hematological malignancies. Still another discloses methods of increasing immunotoxin stability by connecting the antibody chains with a disulfide bond.

Dated: March 2, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–5223 Filed 3–8–04; 8:45 am]

BILLING CODE 4140–01–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. 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.

Carbohydrate-Encapsulated Quantum Dots For Cell-Specific Biological Imaging

Joseph Barchi, Sergey Svarovsky (NCI).