classified as degradation products of the drug substance or reaction products of the drug substance with an excipient and/or immediate container closure system. Impurities arising from excipients present in the new drug product or extracted or leached from the container closure system are not addressed in this revised guidance.

The Q3B(R) guidance has been revised to add information to certain sections and to provide clarification to other sections of the previous guidance. The most important sections that have been revised are:

- The text on reporting, identification, and qualification thresholds.
- The text on the listing of impurities in specifications and a clear distinction between ICH Q3B (listing impurities) and Q6A (setting specifications).
- The deletion of the exception to conventional rounding practice, i.e., the provision recommending no rounding up to 0.1 percent for values between 0.05 and 0.09 percent.
- Attachment 2—an illustration of reporting degradation product results for identification and qualification in an application.
- Attachment 3—a decision tree for identification and qualification of a degradation product.
- Additions and revisions to the previous glossary including definitions for the terms ''unspecified degradation product,'' ''reporting threshold,'' ''identification threshold,'' and ''qualification threshold.''
- References to more recently published ICH guidances (e.g., ''Q3A(R) Impurities in New Drug Substances,'' Q3C Impurities: Residual Solvents,'' and ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances'').

In addition, minor editorial changes were made to improve the clarity and consistency of the document.

This guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any mailed comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: November 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy

[FR Doc. 03–28457 Filed 11–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Customer Satisfaction With Educational Programs and Products of the National Cancer Institute

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 29, 2003, page 32067 and allowed 60 days for public comment. Comments were received from two individuals, both of whom are contractors interested in the potential for conducting portions of the proposed information collection activities. 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: Customer Satisfaction with Educational Programs and Products of the National Cancer Institute. *Type of Information Collection Request:* NEW. *Need and Use of the Information Collection:* The Office of Education and Special Initiatives (OESI) of the National Cancer Institute (NCI) is responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, including prevention, screening, diagnosis, treatment, survivorship, and palliative care; it also manages NCI initiatives that address specific challenges in cancer research and treatment. To help ensure the relevance, utility, and appropriateness of the many educational programs and products that OESI and NCI produce, OESI intends to collect information on customer satisfaction with those products through customer satisfaction surveys. By obtaining information from customers on the extent to which materials satisfy their needs, OESI and NCI will be able to systematically establish and follow a feedback loop that provides useful information to revise and enhance educational programs and products so that they attain maximum relevance, utility, appropriateness, and impact. Data will be collected through various means, including telephone, mail, in-person, and web-based surveys. *Frequency of Response:* On occasion. *Affected Public:* individuals or households, organizations involved in providing health care services. *Type of Respondents:* health care consumers of NCI educational programs or products, including cancer patients and families, health care professionals, cancer control planners, and policymakers. The estimated annual burden hours are as follows: *Estimated Number of Respondents:* 2547; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .167; and *Estimated Total Annual Burden Hours Requested:* 910 (425???). The annualized cost to respondents is estimated at: $17,049. 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.

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: Lenora Johnson, Acting Director, Office of Education and Special Initiatives, National Cancer Institute, 6116 Executive Boulevard, Suite 202, Bethesda, MD 20892–8334, (301) 451–4056.

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: November 6, 2003.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 03–28561 Filed 11–13–03; 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. 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 application 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 application.

Intracellular Trapping of Radionuclides by Enzyme-Mediated Reduction

Fangyu Peng, King Li, Sunil Pandit (CC).

U.S. Provisional Application filed 30 Sep 2003 (DHHS Reference No. E–083–2003/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

The invention provides a novel technique for intracellular trapping of radionuclides for use in cancer therapy and imaging. The technique includes enzyme-mediated intracellular trapping of a radionuclide in a target cell by transfecting the target cell with a transgenic vector encoding a microbial hydrogenase and treating the transfected target cell with a radionuclide. The transgenically expressed microbial hydrogenase catalyzes the reduction of the radionuclide. The reduced radionuclide is trapped intracellularly where its emissions can be detected in radioscintigraphy applications. Emissions from intracellularly trapped radionuclides can also be cytotoxic to the target cell and therefore useful in radiotherapy applications. The invention further provides a reporter mechanism wherein a microbial hydrogenase encoding nucleic acid is included in a vector along with a transgene, both under the control of the same promoter. The detection of emissions from intracellularly reduced and trapped radionuclides is used to monitor transgene expression.

Lutozmyia longipalpis Polypeptides and Methods of Use

Jesus G. Valenzuela, José M.C. Ribeiro (NIAID).

U.S. Provisional Application No. 60/422,203 filed 29 Oct 2002 (DHHS Reference No. E–285–2002/0–US–01).

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov.*

Leishmania parasites are transmitted to their vertebrate hosts by infected phlebotomine sand fly bites. Sand fly saliva is known to enhance Leishmania infection, while immunity to the saliva protects against infection. This invention claims a number of major salivary proteins from the sand fly vector of Leishmania major, Lutzomyia longipalpis, nucleic acids encoding the proteins, vaccines comprising the proteins and/or nucleic acids, and methods of producing an immune response to prevent Leishmaniasis.

The inventors have shown that similar salivary proteins are able to protect vaccinated mice challenged with parasites plus salivary gland homogenates (SGH). The vaccine comprises a DNA vaccine encoding the salivary proteins. In one experiment with mice, the vaccine produced both intense humoral and delayed-type hypersensitivity (DTH) response. The inventors are continuing to experiment preclinically with this vaccine.

Dated: November 4, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–28559 Filed 11–13–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee E—Cancer Epidemiology, Prevention & Control.

Date: December 9–11, 2003.

Time: 7 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Mary C. Fletcher, PhD, Scientific Review Administrator, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8115, Bethesda, MD 20892, (301) 496–7413.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology