3503, FAX: 301–827–2875.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.'' The guidance document describes FDA's thinking on what will be considered separate marketing applications and what will constitute clinical data for purposes of assessing user fees under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h).

This guidance was issued in draft on February 22, 2001 (66 FR 11175) with comments due by March 26, 2001. No comments were received. In the meantime, Congress considered reauthorization of the user fee program. As a result, FDA delayed issuance of the guidance. Now that the program has been reauthorized without change to the relevant language, FDA is issuing the guidance. Other than minor editorial changes, only two changes of note have been made to the guidance. We have reevaluated our policy on pharmacy bulk packages and products for prescription compounding and determined that a separate application is no longer needed for these products unless otherwise noted in the guidance document. Therefore, the subsection entitled ''Pharmacy Bulk Packages and Products for Prescription Compounding'' has been removed. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) may require a new application to be submitted because of a change to the reference listed drug. Therefore, a new subsection was added to clarify the user fee liability.

The 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 mailed comments 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. 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 either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28654 Filed 12–30–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request; California Health Interview Survey 2005

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health 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 August 5, 2004, p. 47450 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: California Health Interview Survey 2005. *Type of Information Collection Request:* New. *Need and Use of Information Collection.* The NCI has sponsored two Cancer Control Modules to the California Health Interview Survey (CHIS), and will be sponsoring a third to be admitted in 2005. The CHIS is a telephone survey designed to provide population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the state. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2005, the third bi-annual survey, is planned for administration to 55,000 adult Californians. The cancer control module, which is similar to that administered in CHIS 2001 and CHIS 2003, will allow NCI to examine trends in breast cancer screening and diagnosis, as well as to study other cancer-related topics, such as diet, physical activity and obesity.

Because California is the most populous and the most racially and ethnically diverse state in the nation, the CHIS 2005 sample will yield adequate numbers of respondents in key ethnic and racial groups, including African Americans, Latinos, Asians, and American Indian/Alaska Natives. The Latino group will include large numbers of Mexican-origin, Central Americans, South Americans, and other Latino subgroups; the Asian group will include large numbers of respondents in the Chinese, Filipino, Japanese, Vietnamese, and Korean subgroups. NCI will compare the CHIS and National Health Interview Survey (NHIS) data in order to conduct comparative analyses and better estimate cancer risk factors and screening among racial/ethnic minority populations. The CHIS sample size also permits NCI to create estimates for ethnic subdomains of the population, for which NHIS has insufficient numbers for analysis. *Frequency of Response:* One-time. *Affected Public:* Individuals. *Type of Respondents:* Adults (persons 18 years of age and older). The annual reporting burden is as follows:

TABLE A.—RESPONDENT AND HOUR BURDEN ESTIMATES FOR CHIS 2005 CANCER CONTROL TOPICAL MODULE

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adult Individuals—Pilot CCM and Demographics	150	1	.17	25.50
Adult Individuals—CCM and Demographics	55,000	1	.17	9,350.00
Totals	.....	.....	.....	9,375.50

The annualized cost to respondents is estimated at: $140,632.50. 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 should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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: Dr. Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344. Bethesda, Maryland 20852–7344, or call non-toll free number (301) 496–8500 or e-mail your request, including your address to *breenn@mail.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: December 21, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–28687 Filed 12–30–04; 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 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.

Use of Anti-Parafibromin Antibodies to Diagnose Hyperparathyroidism-Jaw Tumor Syndrome (HPT–JT) and Parathyroid Cancer

William Simonds, Jian-hua Zhang, and Geoffrey Woodard (NIDDK) U.S. Provisional Application No. 60/531,875 filed 22 Dec 2003 (DHHS Reference No. E–032–2004/0–US–01)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This technology relates to methods of diagnosing cancer using antibodies that specifically bind to parafibromin. Parafibromin appears to be a tumor suppressor. Mutations in the coding sequence, specifically truncations or deletions, might be indicative of cancer or increased susceptibility to cancer. Antibodies targeting this tumor suppressor protein might have utility as a cancer diagnostic or prognostic, either alone, or as part of a kit.

This technology is described, in part, in GE Woodard *et al.*, ''Parafibromin, product of the hyperparathyroidism-jaw tumor syndrome gene HRPT2, regulates cyclin D1/PRAD1 expression.'' Oncogene 2004 Dec 06 (e-pub ahead of print).

Eosinophil-Derived Neurotoxin, an Antimicrobial Protein with Ribonuclease Activity, is an Immunostimulant

De Yang *et al.* (NCI)

U.S. Patent Application No. 10/834,733 filed 29 Apr 2004 (DHHS Reference No. E–191–2003/1–US–01)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

Eosinophil-derived neurotoxin (EDN) has in vitro anti-viral activity that is dependent on its ribonuclease activity. This invention discloses that EDN is a selective chemoattractant and activator of dendritic cells, resulting in dendritic cell migration, maturation, and a production of a wide variety of cytokines. Based on these potent chemotactic and activating effects on dendritic cells, EDN might be useful as a clinical immunoadjuvant for the promotion of immune responses to specific antigens of tumors or pathogenic organisms.

Genes Expressed in Prostate Cancer and Methods of Use

Ira Pastan, Tapan Bera, and Byungkook Lee (NCI)

U.S. Provisional Patent Application No. 60/461,399 filed 08 Apr 2003 (DHHS Reference No. E–148–2003/0–US–01)

PCT Application No. PCT/US04/10588 filed 05 Apr 2004, which published as WO 2004/092213 on 28 Oct 2004