

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than December 6, 2000.

FOR FURTHER INFORMATION CONTACT:

Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Iceberg Industries Corp., 16 Forest Rd., suite 200, P.O. Box 8251, St. John's, Newfoundland, Canada, A1B 3N4.

The permit covers limited interstate marketing tests of products identified as "iceberg water" that deviate from the U.S. standard of identity for bottled water (21 CFR 165.110) in that the source of the water is an iceberg. The test product meets all the requirements of the standard with the exception of the source definition. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

Under this temporary permit, the bottled water will be test marketed as "Borealis Iceberg Water."

This permit provides for the temporary marketing of 150,000 cases of the 24 x 350 milliliters (ml), 150,000 cases of the 12 x 1 liters (L), and another 100,000 cases of the 24 x 500 ml giving 400,000 cases in total. The total fluid weight of the test product will be 1,124,024 gallons or 4,260,000 L. The test product will be manufactured at Iceberg Industries Corp. Water Bottling Plant, Daniel's Point, Trepassy, Newfoundland, Canada, A0A 4B0. The product will be distributed by Iceberg Industries in the United States.

The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101.

This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than December 6, 2000.

Dated: August 23, 2000.

Christine J. Lewis,

Director, Office of Nutritional Products Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition.

[FR Doc. 00-22950 Filed 9-6-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: AIDS Drug Assistance Program (ADAP): ADAP Monthly Client Utilization and Program Expenditures Report (OMB No. 0915-0219)—Revision

State AIDS Drug Assistance Programs (ADAPs), funded under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996 (Pub. L. 104-146), are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including the prevention and treatment of opportunistic infections.

During the last several years, there has been an increasing need for pharmaceuticals among uninsured and underinsured low-income individuals

who are HIV positive or diagnosed with AIDS. Due to the increasing demand, the Division of Service Systems (DSS), Health Resources and Services Administration (HRSA) recognizes the importance of program planning and budget forecasting in order to maximize resources, and proposes to revise the current data collection form to better collect relevant client utilization data and program expenditure information from State ADAPs. This data collection effort is designed to allow DSS/HRSA (the funding agency) to monitor nationwide trends in program growth, client utilization, expenditures and to assess the capacity of State ADAPs to maintain services for clients throughout the fiscal year. The revised form will improve DSS/HRSA's ability to track the prices of HIV/AIDS drugs in order to ensure that State ADAPs are receiving the best price possible, to identify emerging issues and technical assistance needs, and to share information among State ADAPs. It will also assist Title II grantees, State ADAPs, DSS/HRSA staff, and policymakers at both the Federal and State level to better understand the level of client demand for medications and the resources needed to meet those needs.

The revised report will collect time-specific data for the number of enrolled clients, the number of new clients, the number of utilizing clients, the level of funds expended, and the price of HIV/AIDS drugs. A text box is provided to allow State ADAPs to report significant changes to their program, such as a projected budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary changes. On a quarterly basis, State ADAPs will report the purchase price paid on a select number of HIV pharmaceuticals dispensed by each program. DSS/HRSA will continue to compile summary reports that are distributed back to grantees and State ADAPs on a quarterly basis. The data collected is used to guide program planning, formulate budget recommendations, and monitor State ADAPs, especially monitoring the balance between an individual State ADAP's available resources against the client demand for medications. The burden estimates are as follows:

HRSA form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Title II ADAP Grantees (Clients and Expenditures)	54	12	648	0.75	486
Title II ADAP Grantees (Pricing)	54	4	216	0.75	162

HRSA form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Total	54	16	864	0.75	648

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC. 20503.

Dated: August 31, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00-22947 Filed 9-6-00; 8:45 am]

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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 agencies 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 Cumulative Distribution Functions To Determine Protein Purity and Homogeneity

Alfred L. Yergey, Paul S. Blank, Christin M. Sjomeling (NICHD)
DHHS Reference No. E-163-00/0 filed
28 Apr 2000

Licensing Contact: Vasant Gandhi;
301/496-7056 ext. 224;

e-mail: gandhiv@od.nih.gov

Successful solutions to numerous problems in the biochemical sciences depend on the ability to produce "pure" proteins and recognize the degree to which proteins might be modified. Current methods used for assessing purity are relatively nonspecific and insensitive to small differences in molecular weight. The inventors have developed a computer-implemented method and system for nonparametric statistical analysis of matrix-assisted laser desorption ionization (MALDI) protein spectra but is equally applicable to deconvoluted electrospray ionization (ESI) spectra. The invention facilitates assessing protein heterogeneity and detection of otherwise indistinguishable differences in the distribution of molecular weight. A principal advantage is that no additional instrumentation is required beyond that typically included in a mass spectrometry analysis system.

Hsp70-Like ATPase Peptide Binds Chap1/Dsk2

Frederic J. Kaye (NCI)

DHHS Reference No. E-282-99/0 filed
15 Sep 1999

Licensing Contact: Elaine White; 301/496-7056 ext. 282; e-mail:
gesee@od.nih.gov

The current invention embodies the identification of a novel gene and protein, Chap1/Dsk2, a ubiquitin-linked protein which appears to play a vital role in regulating mitosis. Identified also is the conserved 20 amino acid region within the ATPase domain of the protein chaperone STCH, an Hsp70-like protein, which is the binding site for Chap1/Dsk2 and other ubiquitin-linked proteins.

Protein chaperones are essential for cell viability, regulating various cell cycle events including the biosynthesis, folding and unfolding, transport, multiunit assembly, and degradation of cell proteins. Overexpression of protein chaperones, such as STCH, can serve to suppress tumorigenesis and apoptosis. It therefore is believed that the peptide identified as the binding domain of STCH may have potential for use as a therapeutic agent against cancer or various infectious diseases, via modulation of tumorigenesis, apoptosis,

or the multiunit assembly of viral particles such as HIV.

Polypeptides Comprising IL-6 Ligand Binding Receptor Domains and Related Nucleic Acids, Antibodies, Compositions and Methods

W. Carl Saxinger (NCI)

DHHS Reference No. E-061-99/0 filed
27 Aug 1999

Licensing Contact: Richard Rodriguez;
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rodrigur@od.nih.gov

The biological activities of IL-6 include the stimulation of B and T cell growth and differentiation, production of acute-phase proteins by hepatocytes, multilineage hematopoiesis, osteoblast formation, maturation of megakaryocytes and platelet production. An abnormal expression of IL-6 may be involved in the pathogenesis of a variety of diseases, among which are multiple myeloma, rheumatoid arthritis, postmenopausal osteoporosis, chronic autoimmune diseases, Castleman's disease and AIDS. Methods of abrogating the effects of abnormal expression of IL-6 can be made at its site of production or at its target. The inventors of this technology have focused on the latter technique. Using a unique, newly patented, automated peptide array system, the inventors have studied specific sequences potentially involved in protein-protein interactions at the molecular level. This system was used to identify and isolate potential target peptide sequences within the IL-6 receptor molecule. Candidate peptide sequences were identified by direct binding to the IL-6 ligand by optimally displayed IL-6 receptor peptide segments in solid phase form. The specific binding properties of the peptide sequences were verified by using IL-6 heteroantisera, and the peptides have been shown to mitigate or reverse the effects of the above referenced properties of IL-6 in tissue culture.

Receptor-Mediated Uptake of an Extracellular Bcl-XL Fusion Protein Inhibits Apoptosis

Richard J. Youle, Xiuhuai Liu, JoAnn Castelli (NINDS)

DHHS Reference No. E-073-99/0 filed
16 Aug 1999