

As explained in detail in the guidance, there have been repeated instances of DEG poisoning that have led to the development of this guidance. Between 1990 and 1998, DEG poisoning has been reported in Haiti, Argentina, Bangladesh, India, and Nigeria. More recently, in October 2006, there were cases of illness and death in Panama due to DEG poisoning.

The cases involving DEG contamination reveal the following similarities:

- The pharmaceutical manufacturers did not perform full identity testing on the glycerin raw material, including tests to quantify the amount of DEG present and to verify the purity of the glycerin received.

- The pharmaceutical manufacturers of the contaminated products relied on the certificate of analysis (COA) provided by the supplier.

- The origin of the product was not easily apparent from the COA.

FDA has no reason to believe that the U.S. supply of glycerin is affected at the present time. However, because of the serious nature of this potentially fatal problem and the global nature of the pharmaceutical supply chain, FDA is emphasizing in this guidance the importance of testing glycerin for DEG.

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The agency is not seeking comment prior to implementing this guidance because of the potential for a serious public health impact if DEG-contaminated glycerin were to enter the domestic market. The guidance represents the agency's current thinking on this issue. 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. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen 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: April 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-8389 Filed 5-1-07; 8:45 am]

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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 (OMB), 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 OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915-0193)—Extension for 2007 UDS Data Collection

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by HRSA. The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330. The authorizing statute is Section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which is used to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, HRSA requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Universal Report	1,055	1	1,055	28	29,540
Grant Report	145	1	145	18	2,610
Total	1,055	1,100	32,150

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

Dated: April 25, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7-8379 Filed 5-1-07; 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, HHS.

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.

Diagnosing and Treating Cancer Using Beta-Catenin Splice Variants

Description of Technology: This application discloses and claims inventions which may be used alone or together. One group of inventions relates to early detection diagnostic, prognostic and patient monitoring methods ("Diagnostic Methods"). The other group of inventions relates to methods of treatment. Both groups of inventions have particular application with respect to esophageal squamous cell cancers (ESCC) or other types of adenocarcinomas and squamous cell carcinomas.

The Diagnostic Methods are useful in evaluating the status of preneoplastic lesions as well as tumor tissue. Because of this, the methods can be used to track the progression or regression of disease in many types of cell samples from normal to dysplasia to cancer.

The Diagnostic Methods involve measuring the level of one or more pairs of transcripts or the protein products of these pairs of transcripts or the cellular localization of the transcripts or proteins. The primary transcripts or protein products useful in this method are those of the beta-Catenin gene (CTNNB1). In particular, the levels of the 16A and 16B CTNNB1 transcripts or protein products are of importance in carrying out the methods of this patent application. Other gene transcripts or protein products that may be used in conjunction with CTNNB1 16A and 16B to provide additional information are WAF1 (p21) and cMYC.

The treatment methods include employing small interfering RNA molecules (siRNAs) as a means to alter the expression of one or more of these

particular CTNNB1 transcripts. More specifically, preferred siRNA molecules can be used to alter the expression of the CTNNB1 transcripts 16A and/or 16B. These siRNA molecules may be single-stranded (ss) or double-stranded (ds) and may be delivered using a construct capable of producing the siRNA molecule upon delivery to the target cell.

Applications: Diagnostic or prognostic methods for squamous cell cancers and adenocarcinomas; Monitoring therapeutic response during and after patient treatment; Development of cancer treatments; Basic research to further elucidate the role of beta catenin in signal transduction pathways and carcinogenesis.

Development Stage: The use of beta catenin transcripts to provide prognostic or diagnostic information remains the subject of research but early patient data is found in the article in Genes Chromosomes & Cancer listed below. Work related to the use of siRNA as a treatment strategy remains in its early stages of research and has not yet progressed to clinical trials.

Inventors: Mark J. Roth and Konrad Huppi (NCI).

Publications:

1. The patent application has been published as WO 2006/086772 A2 on 17 August 2006.

2. MJ Roth *et al.* beta-Catenin splice variants and downstream targets as markers for neoplastic progression of esophageal cancer. Genes Chromosomes Cancer. 2005 Dec;44(4):423-428.

3. SE Martin *et al.* Multiplexing siRNAs to compress RNAi-based screen size in human cells. Nucleic Acids Res. 2007 Mar 28; E published ahead of print, doi:10.1093/nar/gkm141.

4. A Thiele *et al.* AU-rich elements and alternative splicing in the beta-Catenin 3' UTR can influence the human beta-Catenin mRNA stability. Exp Cell Res. 2006 Jul;312:2367-2378.

Patent Status:

PCT/US2006/05032 filed 10 Feb 2006 and published as WO 2006/086772 on 17 Aug 2006, currently pending, entitled "Method of Diagnosing and Treating Cancer Using Beta Catenin Splice Variants" (HHS Reference No. E-018-2005/2-PCT-01);

U.S. Provisional Application No. 60/667,084 filed 30 Mar 2005, now abandoned (HHS Reference No. E-018-2005/1-US-01);

U.S. Provisional Application No. 60/652,154 filed 10 Feb 2005, now abandoned (HHS Reference No. E-018-2005/0-US-01).

Biological Materials Availability:

Biological materials related to this technology are available and include

those referred to in the following publications as well as a series of recently established aptamers capable of specific binding to the CTNNB1 protein.

1. MJ Roth *et al.* Cytologic detection of esophageal squamous cell carcinoma and precursor lesions using balloon and sponge samplers in asymptomatic adults in Linxian, China. Cancer. 1997 Dec 1;80(11):2047-2059.

2. Q-J Pan *et al.* Cytologic detection of esophageal squamous cell carcinoma and its precursor lesions using balloon samplers and liquid-based cytology in asymptomatic adults in Linxian, China. ACTA Cytologica (In Press).

3. MJ Roth *et al.* A study of beta-catenin splice variants and associated downstream targets as markers for neoplastic progression of squamous cell carcinoma of the esophagus. Genes Chromosomes Cancer. 2005 Dec;44(4):423-428.

4. PJ Limburg *et al.* Randomized, placebo-controlled esophageal squamous cell cancer chemoprevention trial of selenomethionine and celecoxib. Gastroenterology. 2005 Sept;129(3):863-873.

Licensing Availability: This application is available for license on a non-exclusive or exclusive basis.

Licensing Contact: Susan S. Rucker, Esq.; 301/435-4478; ruckersu@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute, Division of Cancer Epidemiology and Genetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a method of diagnosing and treating cancer using beta-Catenin splice variants. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information. 8356

Dated: April 25, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-8356 Filed 5-1-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of 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 a meeting of the