applicability of the Federal Import Milk Act (FIMA) to imported milk and cream.

DATES: Submit written or electronic comments on the draft revised CPG by November 29, 2004. General comments on agency guidance documents are welcome any time.

ADDRESSES: Submit written requests for single copies of the draft revision of the CPG entitled ''Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Esther Lazar, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1485, FAX: 301–436–2632.

SUPPLEMENTARY INFORMATION:

I. Background

The FIMA (21 U.S.C. 141 *et seq.*) prohibits the importation into the United States of milk and cream without a valid permit from the Secretary of Health and Human Services. FDA is revising the CPG to clarify and update its policy regarding which dairy products require permits under the FIMA. As explained in the draft CPG, FDA intends to consider the following dairy products to be subject to the FIMA's permit requirement for importation into the United States:

- Milk, lowfat milk, skim milk, fortified milk, flavored milk, concentrated milk, evaporated milk, sweetened condensed milk, ultra filtered milk.
- Cream, half-and-half, heavy cream, light cream, and light whipping cream.

FDA does not intend to require a FIMA permit for the following dairy products:

- Sour cream, cultured milk, acidified milk, yogurt, cheese, ice cream, and eggnog.
- Dried milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, and other dehydrated milk products.
- Any dairy product for which a permit is otherwise required, if it has been processed and packaged in hermetically sealed containers so as to be commercially sterile in accordance with the requirements of 21 CFR 108.35 and 21 CFR part 113.

FDA has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft guidance is being issued as a level 1 draft guidance consistent with GGPs. The draft revised CPG represents the agency's current thinking on the applicability of the FIMA to imported milk and cream. 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 statues and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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

A copy of the draft revised CPG may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the draft revised CPG and may be accessed at *http://www.fda.gov/ora* under ''Compliance Reference.''

Dated: October 22, 2004.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–24153 Filed 10–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans

SUMMARY: In compliance with the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

Proposed Collection: Title: Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will obtain information on policies, programs, and practices for colorectal cancer screening among health plans in the U.S. The purpose of the study is to assess (1) Health plan policies, programs, and practices for colorectal cancer screening; (2) health plan activities in response to the National Committee on Quality Assurance's new Health Employer Data Information Set measure for colorectal cancer screening; and (3) characteristics of health plans and plan policies and activities that may be associated with higher rates of colorectal cancer screening. A questionnaire will be administered by mail or Internet using a national sample of health plans. Study participants will be health plan medical directors or administrators, and they will select their preferred response mode. Burden estimates are as follows:

Estimated number respondents	Estimated number responses per respondent	Average burden hours per response	Estimated total annual burden hours
520	1	0.333	173

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (a) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Send comments to Carrie N. Klabunde, Ph.D., Epidemiologist, National Cancer Institute, EPN 4005, 6130 Executive Boulevard, Bethesda, Maryland 20892–7344. Telephone: (301) 402–3362; Fax: (301) 435–3710 E-mail: *ck97b@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 18, 2004

Rachelle Ragland-Green,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–24165 Filed 10–28–04; 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.

Mouse Monoclonal Antibody (4G11) Against Insulin-Like Growth Factor I Receptor

Peter Nissley, Peta-Gay Jackson-Booth, Cheryl Terry, Brett Lackey, Martyna Lopaczynska (NCI)

DHHS Reference No. E–342–2004/0–US–01

Licensing Contact: John Stansberry; (301) 435–5236; *stansbej@mail.nih.gov.*

The insulin-like growth factor I receptor (IGF–IR) is emerging as a molecular target for cancer treatment. Prospective studies in humans provide evidence for a relationship between circulating levels of both IGF–I and IGF binding protein 3 (IGFBP–3) and the risk for the development of cancers of the prostate, breast, lung, and colon. Many human cancers express or over-express components of the IGF signaling pathway, in particular IGF–II and the IGF–I receptor. This technology describes a mouse monoclonal antibody that binds the insulin-like growth factor I receptor. The IGF–IR monoclonal antibody 4G11 blocks binding of IGF–I to its receptor and promotes down regulation of the receptor in MCF–7 breast cancer cells, MG–63 osteosarcoma cells and a panel of colon cancer cells. Additionally, 4G11 stimulated down-regulation of the IGF–I receptors in MCF–7 cells results in inhibition of Akt and MAPK activation by IGF–I. This monoclonal antibody has utility as a laboratory reagent for immunoprecipitations, and as an inhibitor of the IGF–I signaling pathway. A humanized form of monoclonal antibody 4G11 would potentially have utility as a therapeutic to treat a variety of cancers in which IGF–IR signaling has been shown to be important. This research is partially described in Horm Metab Res 2003; 35: 850–856.

Beta-Glucuronidase Cleavable Prodrugs of O6-Alkylguanine-DNA Alkyltransferase Inactivators

Robert C. Moschel *et al.* (NCI)

U.S. Provisional Application filed 08 Sep 2004 (DHHS Reference No. E–307–2004/0–US–01)

Licensing Contact: George Pipia; (301) 435–5560; *pipiag@mail.nih.gov.*

The present invention relates to prodrugs of inactivators of O6-alkylguanine-DNA alkyltransferase. The prodrugs are cleaved by the beta-glucuronidase enzyme found in tumor cells or co-administered to the patient, and the drugs are targeted for use in cancer treatment in combination with antineoplastic alkylating agent such as 1,3-bis(2-chloroethyl)-1-nitrosouria or temozolomide.

Transcytosis of Adeno-Associated Viruses

John A. Chiorini and Giovanni Di Pasquale (NIDCR)

U.S. Provisional Application filed 08 Sep 2004 (DHHS Reference No. E–298–2004/0–US–01)

Licensing Contact: Jesse Kindra; (301) 435–5559; *kindraj@mail.nih.gov.*

The invention relates to a method for delivering nucleic acids to a variety of cells including those of the gut, kidney, lung and central nervous system. The underlying cells of such organs are covered by a barrier of endothelial or epithelial cells which can limit the transfer of nucleic acids, or other potentially therapeutic agents, to the underlying target cells. To overcome this limitation, the method employs certain members of the parvovirus family to transcytose the barrier cells. During transcytosis, the virus passes through these barrier cells and can infect cells of the underlying layer. Therefore, this method could facilitate the transfer of nucleic acids to cells that currently available viral vectors are unable to reach.

The method could be applied to the treatment of neurodegenerative diseases such as Parkinson's, Alzheimer's, Huntington's, lysosomal storage diseases, the dominant spinal cerebellar ataxias, and Krabbe's disease without the need for stereotactic injection. The method could potentially also be used in the treatment of genetic muscle disorders such as muscular dystrophy. Several of the viruses described in the invention are serologically distinct and could be used in patients who have developed an immune response to other vectors.

Multimeric Protein Toxins to Target Cells Having Multiple Identifying Characteristics

Stephen Leppla (NIAID), Shi-hui Liu (NIAID), and Thomas Bugge (NIDCR)

U.S. Provisional Application No. 60/543,417 filed 09 Feb 2004 (DHHS Reference No. E–059–2004/0–US–01)

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

This technology relates to multimeric bacterial protein toxins which can be used to specifically target cells. Specifically, this is a modified recombinant anthrax toxin protective antigen (PrAg) that has been modified in several ways. First, the PrAg can be activated both by a metalloproteinase (MMP) and by urokinase plasminogen activator (uPA). Second, the native PrAg