FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr. Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The National Strategy for Pandemic Influenza was issued by President Bush in November 2005. This National Strategy identifies the U.S. Department of Health and Human Services (HHS) as the lead for medical response and is intended to guide our nation's preparedness and response to pandemic influenza.

The Implementation Plan for the National Strategy for Pandemic Influenza (the Implementation Plan) was issued by the President on May 3, 2006. The Implementation Plan translates the Strategy into more than 300 actions for Federal departments and agencies and sets expectations for State and local governments and other non-Federal entities. FDA's Center for Biologics Evaluation and Research is the lead for the vaccine action items under section 6.1.13.9 parts (1) and (3) of chapter 6 of the Implementation Plan. This section, in part, states that HHS, in coordination with the Department of Defense, the Veteran's Administration, and in collaboration with State, territorial, tribal, and local partners, shall develop and refine mechanisms to: (1) Track adverse events following vaccine and antiviral administration; and (2) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic, within 18 months.

FDA conveyed in our May 31, 2007, Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines (72 FR 30599), that all sponsors who seek licensure of a pandemic influenza vaccine should expect FDA to seek their involvement in working with FDA and other governmental agencies on plans to collect additional safety and effectiveness data, such as through epidemiological studies, when the vaccine is used (see *http://www.fda.gov/cber/gdlns/panfluvac.htm*). FDA and the Centers for Disease Control and Prevention are engaged in discussions about adverse events surveillance during early use of influenza vaccines for pre-pandemic and pandemic situations. Relevant to the actions outlined in the preceding paragraph, we are inviting vaccine manufacturers who are pursuing the development of pre-pandemic and pandemic influenza vaccines, as well as other interested persons, to provide comments and information concerning mechanisms to track adverse events following vaccination, and the development of protocols to study effectiveness of influenza vaccines during a pandemic.

Specifically, we are requesting information on the design of potential studies to assess the effectiveness of influenza vaccine in a pandemic situation, including comments on the potential usefulness of randomized trials, case control studies, or additional study designs, as well as, potential endpoints. In addition, we are seeking comments on organizations and entities, such as managed care organizations, or other public or private entities that may be able to partner with manufacturers and sponsors to assess safety and effectiveness.

We are requesting comments and information to help us understand the complex issues encountered in trying to obtain these data during a pandemic. Your comments and information might assist us in the development of additional guidance documents for the conduct of postmarketing safety surveillance and effectiveness studies for pandemic influenza vaccines.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and information 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 the brackets in the heading of this document. A copy of this document 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 National Strategy for Pandemic Influenza, issued November 2005, and the Implementation Plan for the National Strategy, issued May 3, 2006, at (*http://www.pandemicflu.gov/plan/federal/index.html*).

Dated: September 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19577 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper 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.

Proposed Project: HRSA AIDS Drug Assistance Program Quarterly Report—(OMB No. 0915–0294): Revision

HRSA's AIDS Drug Assistance Program (ADAP) is funded through Part B of Title XXVI of the Public Health Service Act, the Ryan White HIV/AIDS Program, which provides grants to States and Territories. The ADAP provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 States, the District of Columbia, Puerto Rico, and several Territories receive ADAP grants. As part of the funding requirements, ADAP grantees submit quarterly reports that include information on patients served, pharmaceuticals prescribed, pricing, and other sources of support to provide AIDS medication treatment, eligibility

requirements, cost data, and coordination with Medicaid. Each quarterly report requests updates from programs on number of patients served, type of pharmaceuticals prescribed, and prices paid to provide medication. The first quarterly report of each ADAP fiscal year (due in July of each year) also requests information that only changes annually (e.g., State funding, drug formulary, eligibility criteria for enrollment, and cost-saving strategies including coordinating with Medicaid).

The quarterly report represents the best method for HRSA to determine how ADAP grants are being expended and to provide answers to requests from Congress and other organizations.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
1st Quarterly Report	57	1	57	3	171
2nd, 3rd, & 4th Quarterly Reports	57	3	171	1.5	256.5
Total	57	.....	228	.....	427.5

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 28, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7–19599 Filed 10–3–07; 8:45 am]

BILLING CODE 4165–15–P

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.

Hepatitis C Virus Cell Culture System

Description of Technology: Hepatitis C virus (HCV) infection causes chronic liver disease and is a major global health problem with an estimated 170 million people affected worldwide and 3–4 million new cases every year. Therapeutic advances will be greatly aided by the ability of researchers to successfully replicate and characterize the virus in vitro. The study of HCV replication has, however, been hindered by the lack of an efficient virus culture system. One approach, using cell culture adaptive mutations in the viral RNA has been found to significantly enhance HCV virus production, but it has been difficult to define which stage of the viral lifecycle is affected by a given adaptive mutation.

NIH researchers have now developed a single-cycle virus production system that allows the stage of the viral lifecycle affected by a specific adaptive mutation to be determined. They have isolated a unique subclone of Huh 7 Hepatoma cells, S29, that permits HCV replication and infectious virion release, but is resistant to infection by HCV. This permits the use of single cycle growth studies, and removes the confounding effects of virus re-infection allowing progress to be made on structure/function studies, or on studies of the effects of drugs on replication and virus assembly.

Applications: HCV drug discovery; HCV single-cycle virus studies; HCV structure/function studies.

Market: HCV research.

Inventors: Suzanne U. Emerson, Robert H. Purcell, Rodney Russell (NIAID).

Patent Status: HHS Reference No. E–324–2007/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Chekesha S. Clingman, Ph.D.; 301/435–5018; *clingmac@mail.nih.gov*.

Use of CpG Oligodeoxynucleotides To Induce Epithelial Cell Growth

Description of Invention: Wound repair is the result of complex interactions and biologic processes. Three phases have been described in normal wound healing: acute inflammatory phase, extracellular matrix and collagen synthesis, and remodeling. The process involves the interaction of keratinocytes, fibroblasts and inflammatory cells at the wound site. The sequence of the healing process is initiated during an acute inflammatory phase with the deposition of provisional tissue. This is followed by re-epithelialization, collagen synthesis and deposition, fibroblast proliferation, and neovascularization, all of which ultimately define the remodeling phase. These events are influenced by growth factors and cytokines secreted by inflammatory cells or by the cells localized at the edges of the wound.

Tissue regeneration is believed to be controlled by specific peptide factors which regulate the migration and proliferation of cells involved in the repair process. Thus, it has been proposed that growth factors will be useful therapeutics in the treatment of wounds, burns and other skin disorders. However, there still remains a need for additional methods to accelerate wound healing and tissue repair.

This application claims methods of increasing epithelial cell growth. The methods include administering a therapeutically effective amount of a CpG oligodeoxynucleotide (ODN) to induce epithelial cell division. Also claimed are methods of inducing wound healing. The method includes treating the wound with a CpG oligonucleotide, thereby inducing wound healing. The wound can be any type of wound, including trauma or surgical wounds. The CpG ODN can be applied systemically or locally.