

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA imported products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Non-Tobacco .....	3,406	1,089	3,709,134	<sup>2</sup> 0.14	519,279
Tobacco .....	330	68	22,440	<sup>2</sup> 0.14	3,142
Total .....					522,421

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> (8 minutes).

The hourly burden for this information collection is based on FDA's averaging of data obtained during a survey of nine representative filers nationwide and FDA's experience. For purposes of comparison of hourly burden, the filers also were requested to provide the same information with regard to filing entries manually. FDA felt that the average time for completing either electronic or manual entries was very similar.

Based on data collected by FDA's survey of nine filers and its experience, the total annual burden to the import community to submit information electronically for 3,731,574 average annual responses was 522,421 hours. The previously OMB-approved hours per response (0.14 hours) are expected to remain the same.

This burden includes the time FDA estimates it will take respondents to compile and provide documents to FDA for those entries where FDA cannot make an admissibility decision based on the electronic data alone. Based on the survey of nine filers and FDA's past experience, FDA estimates that there will be no additional costs to provide import data electronically to FDA, as filers already have equipment and software in place to enable them to provide data to USCS via the automated system. Therefore, no additional software or hardware need be developed or purchased to enable filers to file the FDA data elements at the same time they file entries electronically with USCS.

Dated: March 7, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; 60-Day Comment Request; Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR)**

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

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

**To Submit Comments and For Further Information:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Julie Schneider, Program Director, Center for Global Health, National Cancer Institute, 9609 Medical Center Dr., RM 3W564, Rockville, MD 20850 or call non-toll-free number 240-276-5795 or Email

your request, including your address to: [schneidj@mail.nih.gov](mailto:schneidj@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**DATES:** *Comment 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.

*Proposed Collection:* Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NIMH, NINDS, OAR), 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This submission is a request for OMB to approve the Evaluation of National Institutes of Health (NIH) International Bilateral Programs for three years. The bilateral awards are made through the Funding Opportunity Announcement mechanism and administrative supplements, meaning they are funded by set-aside funds that are separate from the general pool of research program grant funds used to support investigator initiated research at NIH. The bilateral programs to be evaluated are the U.S.-China Program for Biomedical Research Cooperation, U.S.—India Bilateral Collaborative Research Partnerships on the Prevention of HIV/AIDS and Co-morbidities, U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities, and U.S.-South Africa Program for Collaborative Biomedical Research. These programs are funded and administered by various combinations of the following institutes: Fogarty International Center (FIC), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke

(NINDS), and the Office of AIDS Research (OAR). While these programs differ, their underlying concept is the same; they require U.S. scientists to collaborate with scientists from other countries in order to conduct scientifically meritorious investigations of mutual interest to both countries. The

proposed evaluation requests information about (1) accomplishments of the awards, (2) unique findings or opportunities due to the international collaborations, and (3) successes and challenges of these collaborations. The information will be collected one year into the award and at the end of the

award, when possible. This information is needed to evaluate the effectiveness of these programs across NIH.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 128.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Principal Investigators Administrative Supplements .....	24	1	1	24
Principal Investigators Other Mechanisms .....	52	2	1	104

Dated: March 7, 2014.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, National Institutes of Health.*

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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, 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. 209 and 37 CFR part 404 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.

**FOR FURTHER INFORMATION CONTACT:** 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.

#### **Rabies Vaccine for the Oral Immunization of Domesticated Animals, Wildlife and Feral Animals**

*Description of Technology:* This invention, developed by the CDC and collaborators, entails a live, attenuated recombinant rabies virus vaccine that can elicit an effective anti-rabies immune response in animal recipients. Inoculation with a live, attenuated, rabies virus allows for the optimized production of immunity in the absence of pathogenicity. Oral administration of rabies vaccines is often a preferred route of vaccine delivery because it is most effective in wildlife. Unfortunately, availability of an oral vaccine for canines has been a significant hurdle to date.

This vaccine technology could be used for immunization of stray dogs by an oral route. In developing nations, more than 90% of human exposure events and 99% of human deaths due to rabies are caused by rabid dogs. Using this vaccine with a broadly implemented oral vaccination strategy provides a promising opportunity for reducing transmission of rabies between stray dogs and, thereby, increasing protection for people.

#### *Potential Commercial Applications:*

- Wildlife and humane shelter rabies prevention and control programs
- Improved rabies vaccines for pets and livestock
- Humane, targeted approach to elimination of rabies reservoirs in feral animal populations

#### *Competitive Advantages:*

- Safe and effective
- Oral immunization is the most practical and efficient method of rabies vaccination of wildlife and feral animals
- Vaccine has demonstrated protection in vivo
- Recombinant, non-neuroinvasive virus expressing a neuroinvasive

glycoprotein and/or pro-apoptosis gene safely induces a robust and desirable immunological response

#### *Development Stage:*

- In vitro data available
- In vivo data available (animal)

*Inventors:* Charles E. Rupprecht (CDC), et al.

*Intellectual Property:* HHS Reference No. E-470-2013/0—U.S. Patent No. 7,074,413 issued 11 Jul 2006.

*Licensing Contact:* Whitney Blair, J.D., M.P.H.; 301-435-4937; [whitney.blair@nih.gov](mailto:whitney.blair@nih.gov).

#### **Cable-Line Safety System: Electro/Hydraulic Emergency Stop Device for a Winch, Drum or Capstan**

*Description of Technology:* This CDC-developed invention entails a system of electrical and hydraulic circuits used to stop a rotating winch in an emergency. Amongst other locations, one stop switch can be positioned on a capstan winch horn. This location makes it available to a victim entangled in rope being retrieved on a gypsy drum. As designed, the stop circuit could be used with an electrically, hydraulically or pneumatically operated winch. A variant of this safety system has been successfully tested on a purse seining fishing vessel in Alaskan waters.

#### *Potential Commercial Applications:*

- Retrofitting existing winches for additional safety and adherence to possible future regulations
- Specifically designed and tested for the marine/fishing industries
- Applications in mining, construction, forestry, and/or off-road automotive industries
- Workers' well-being concern groups
- Insurers of fishing vessels; also mining, construction and forestry operations
- Manufacturers of cable reel trailers and wire-drawing machinery

#### *Competitive Advantages:*