There will be 2,890 respondents for a one-time survey total of 2,890 annual responses. The hours per response is estimated to be .33 hours. Thus the total annual burden is estimated to be 953.7 hours. A 60 percent response rate is expected.

Dated: July 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16806 Filed 7–8–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0124]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by August 9, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title "Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act—(OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Smokeless Tobacco Act (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires that manufacturers, packagers, importers, distributors, and retailers (in limited circumstances) of smokeless tobacco products include one of four specified health warning label statements on product packages and in advertisements.[1] The Smokeless Tobacco Act, as amended, also requires smokeless tobacco product manufacturers, importers, distributors, and certain retailers to submit a plan to FDA specifying the method to rotate, display, and distribute the specified health warning label statements required to appear in advertising and packaging. FDA is required to review each plan submitted and approve the plan if it provides for rotation, display, and distribution of warnings in compliance with the requirements of the Smokeless Tobacco Act. To the best of FDA's knowledge, all of the affected companies have previously submitted similar plans to the Federal Trade Commission (FTC), which had authority to implement the requirements of the Smokeless Tobacco Act prior to the Tobacco Control Act's amendments. However, because the requirements of the Smokeless Tobacco Act have been revised and because FDA now has authority to implement the Smokeless Tobacco Act, each affected company will be required to submit a new plan to FDA instead of FTC. The Tobacco Control Act's amendments to the Smokeless Tobacco Act are effective on June 22, 2010.

On August 7, 2007, FTC published a 30-day notice (72 FR 44138) announcing an opportunity for public comment and that the information collection would be sent to OMB for review. Based on FTC's previous experience with the submission of rotational plans and FDA's experience with smokeless tobacco companies (e.g., correspondence associated with user fees under section 919 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act), FDA estimates that there are 14 companies affected by this information collection. To account for the entry of new smokeless tobacco companies who may be affected by this information collection, FDA is estimating the total number of respondents to be 20.

When FTC originally implemented the rotational plan requirements in 1986, the Smokeless Tobacco Council, Inc., indicated that the six companies it represented would require 700–800 hours in total (133 hours each) to complete an initial rotational plan, involving multiple brands, multiple brand varieties, and multiple forms of both packaging and advertising. When FTC requested an extension of their PRA clearance in 2007, FTC decreased the estimate for submitting an initial plan from 143 hours to 60 hours, accounting for increased computerization and improvements in electronic communication over the subsequent 20 years since the Smokeless Tobacco Act was enacted. FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable. However, because the requirements of the new Smokeless Tobacco Act are unfamiliar to industry, FDA is increasing the time estimate for submitting initial plans to 100 hours.

In the **Federal Register** of March 16, 2010 (75 FR 12552), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on this information collection.

FDA estimates the burden of this collection of information as follows:

[1] The warnings themselves disclose information completely supplied by the Federal Government. As such, the disclosure does not constitute a "collection of information" as it is defined in the regulations implementing the PRA, nor, by extension, do the financial resources expended in relation to it constitute paperwork "burden." (*See* 5 CFR 1320.3(c)(2).)

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Submission of rotational plans for health warning label statements	20	1	20	100	2,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16805 Filed 7–8–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control

Special Emphasis Panel (SEP): Preparedness and Emergency Response Learning Centers (PERLC) Panel, Request for Applications (RFA) TP10–1001, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the aforementioned meeting:

Times and Dates: 8:30 a.m.–5 p.m., July 27, 2010 (Closed). 8:30 a.m.–5 p.m., July 28, 2010 (Closed). 8:30 a.m.–5 p.m., July 29, 2010 (Closed).

Place: The W Atlanta Hotel-Perimeter, Perimeter Center West, Atlanta, Georgia 30346, Telephone: (770) 396–6800.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Preparedness and Emergency Response Learning Centers (PERLC) Panel, RFA TP10–1001."

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Shoukat Qari, Senior Scientific Program Official, Extramural Research Program, Office of Public Health Preparedness and Response, 1600 Clifton Road, Mailstop D–44, Atlanta, Georgia 30333, Telephone: (404) 639–7938, E-mail: *SQari@cdc.gov.*

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 2, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–16741 Filed 7–8–10; 8:45 am]

BILLING CODE 4163–18–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.

Identification of Cancer Stem Cells

Description of Invention: Cancer stem cells (CSC) are thought to be responsible for cancer initiation, maintenance, and therapeutic failure. A hallmark of stem cells is self-renewal via asymmetric cell division (ACD) into daughter stem-cells and cells predestined for differentiation. Demonstration of fundamental stem-cell's traits such as ACD in cancers is lacking. Label retaining cells are thought to be enriched for stem-like cells. Label retaining cells are thought to be the results of either very slow cycling cells and/or cells undergoing ACD. This invention is directed to the identification, isolation and purification of cancer stem cells by detecting asymmetrically dividing cells and/or label retaining cells. Detection of asymmetric cell division via non-random chromosomal cosegregation (ACD–NRCC) in various human cancers defines a unique and novel class of universal cancer stem cells, and potentially suggests a novel mechanism of carcinogenesis. The isolation of CSC might be used as a basis for a potential new strategy in cancer therapeutics. The invention also might have some implications in genetics and regenerative medicine.

Applications

- This invention may provide a novel way to target various cancers for treatment.
- This invention maybe also useful in regenerative medicine, i.e. spinal cord injury (regeneration of neurons), Alzheimer (regeneration of neurons) and Parkinson's disease regeneration of neurons).

Development Status: Pre-clinical stage of development.

Market

- Cancer is the second leading cause of death in the U.S. The National Cancer Institute estimates the overall annual costs for cancer in the U.S. at $107 billion; $37 billion for direct medical costs, $11 billion for morbidity costs (cost of lost productivity), and $59 billion for mortality costs.
- According to statistics gathered by the National Institutes of Health, more than 10,000 Americans experience spinal cord injuries each year and more than 200,000 are living with permanent paralysis in their arms or legs due to spinal cord injury.
- Parkinson's disease affects some four million patients worldwide. Approximately 50,000 Americans are diagnosed with Parkinson's disease each year. Alzheimer Disease is estimated to affect 5.09 million patients by 2010.

Inventors: Itzhak Avital, Hong-Wu Xin, Danielle M. Hari (NCI)

Publication: Manuscript submitted.