EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form mode	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Adult SAQ	21,000	2,450	19.56	47,922
Diabetes care SAQ	1,800	90	19.56	1,760
Permission forms for the MEPS–MPC	15,000	3,900	19.56	76,284
Subtotal for the MEPS–HC	52,800	62,690	na	1,226,216
MEPS–MPC:				
Home care for health care providers questionnaire	441	239	14.24	3,403
Home care for non-health care providers questionnaire	23	13	19.56	254
Office-based providers questionnaire	13,665	6,605	14.24	94,055
Separately billing doctors questionnaire	12,450	1,245	14.24	17,729
Hospitals questionnaire	5,402	2,926	14.24	41,666
Institutions (non-hospital) questionnaire	72	9	14.24	128
Pharmacies questionnaire	7,760	9,040	14.24	128,730
Subtotal for the MEPS–MPC	39,813	20,077	na	285,965
Grand Total	92,613	82,767	na	1,512,181

*Based upon the mean of the average wages for Healthcare Support Workers, All Other (31–9099) and All Occupations (00–0000), Occupational Employment Statistics, May 2007 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.*

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this information collection. The cost associated with the design and data collection of the MEPS–HC and MEPS–MPC is estimated to be $47.6 million in each of the next three fiscal years.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost (in million)	Annualized cost (in million)
Sampling Activities	$2.79	$0.93
Interviewer Recruitment and Training	8.52	2.84
Data Collection Activities	86.7	28.9
Data Processing	21.39	7.13
Production of Public Use Data Files	19.53	6.51
Project Management	3.93	1.31
Total	142.8	47.6

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 27, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–10406 Filed 5–5–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0487] (formerly Docket No. 2007D–0260)

Compliance Policy Guide; ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Compliance Policy Guide (CPG) entitled ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The CPG provides written guidance to FDA's and

Customs and Border Protection's (CBP's) staff on enforcement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States.

DATES: Submit written or electronic comments concerning the CPG at any time.

ADDRESSES: Submit written comments on the CPG 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

Submit written requests for single copies of the CPG 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.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866–521–2297.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 7, 2008 (73 FR 66411), FDA announced the availability of a draft CPG entitled ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' After considering the one comment received, FDA revised the CPG, with CBP concurrence, where appropriate. The revised CPG provides written guidance to FDA's and CBP's staff on enforcement of section 307 of the Bioterrorism Act and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States.

FDA is issuing this CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on its enforcement policy concerning prior notice. 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 regarding this document. Submit a single copy of electronic copies 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. The CPG and 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

An electronic version of the CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: April 29, 2009.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. E9–10556 Filed 5–4–09; 4:15 pm]

BILLING CODE 4160–01–S

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.

Small Molecule Activators of Human Pyruvate Kinase for Treatment of Cancer and Enzyme-Deficient Hemolytic Anemia

Description of Technology: NIH investigators have discovered a series of small compounds with the potential to treat a variety of cancers as well as hemolytic anemia. Contrary to most cancer medications, these molecules can be non-toxic to normal cells because they target a protein specific to the metabolic pathways in tumors, thus representing a significant clinical advantage over less-specific chemotherapeutics.

The invention described here is a series of small molecules that activate pyruvate kinase (PK) isoform M2. PK–M2 is a critical metabolic enzyme that is affected in all forms of cancer. Inactivation of PK–M2 leads to a buildup of metabolic intermediates inside the cell. Tumor cells require a buildup of metabolic intermediates in order to undergo rapid cell growth and proliferation. Hence, activation of PK–M2 in tumor cells may prevent the buildup of metabolic intermediates and thereby stall tumor cell proliferation or destroy the tumor cells. Further, while in normal adult cells only PK isoforms R, L, or M1 are active, in all tumors only PK–M2 is active. Therefore, PK–M2 activation would affect only tumor cells, and small-molecule PK–M2 activators are not expected to be toxic to healthy cells.

In addition, in patients with PK–R deficiency the buildup of metabolic intermediates in red blood cells ultimately leads to the loss of water from the cells and cell death. Small-molecule induced activation of PK–R in PK-deficient red blood cells may enhance vitality of these cells and decrease or eliminate enzyme-deficient hemolytic anemia in a patient.

Applications: Therapeutic for cancer; Therapeutic for enzyme-deficient hemolytic anemia.

Development Status: Early stage.

Market: In the United States in 2008, approximately 1.4 million people were diagnosed with cancer. In addition, approximately 12,000 people in the United States are chronically affected by PK-deficient hemolytic anemia.

Inventors: Craig J. Thomas et al. (NHGRI).

Publications: In preparation.

Patent Status: U.S. Provisional Application No. 61/104,091 filed 09 Oct 2008 (HHS Reference No. E–326–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Steve Standley, PhD; 301–435–4074; *sstand@od.nih.gov.*