manufacturer, explain the reasons for the delay, and discuss the time frame for completing the review.

Third, the comment asked whether ''the manufacturing facility is approvable or to be re-inspected'' if the dispute is not resolved at the end of the tier-two DR stage.

FDA Response—As described in the guidance, it is FDA's intention to resolve through the DR process all issues raised by the manufacturer. If FDA agrees with the manufacturer, the Form FDA 483 that prompted the request for formal dispute resolution would be revised or rescinded. If FDA disagrees with the manufacturer's request, the issues raised in the Form FDA 483 stand and FDA would expect compliance with the applicable CGMP requirements, which FDA may verify by re-inspection.

Dated: July 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17577 Filed 7–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Public Health Service; The National Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS) (NCI)

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 (OMB) for review and approval.

Proposed Collection: Title: The National Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS); *Type of Information Collection Request:* NEW; *Need and Use of Information Collection:* The purpose of SPARCCS is to identify the beliefs, knowledge, attitudes, and practices of primary care physicians and cancer specialists regarding the components described by the Institute of Medicine's (IOM) 2005 report that described the essential components of cancer survivorship care within a health care delivery system. These data will inform the process of standardization of survivorship care practices; augment the data collected in other cancer survivorship studies such as the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS), and the Cancer Research Network; and monitor the progress made toward achieving NCI strategic goals of improving the quality of cancer care across the cancer control continuum. Two questionnaires, one sent to primary care physicians and one sent to medical oncologists, will be administered by mail to a randomly selected national sample of 2,200 physicians. Study participants will be 1,100 practicing physicians who are family practitioners, general internists, and obstetrician/gynecologists and 1,100 medical oncologists. *Frequency of Response:* Once. *Affected Public:* Individuals and Businesses. *Type of Respondents:* Primary care and medical oncology physicians practicing in a non-federal facility. The annual reporting burden is estimated at 903 hours as shown in Table 1. The total burden hours is estimated at 1,808 hours over the two year field period of the study. There are no capital, operating or maintenance costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Receptionists	Screener	2,033	1	5/60	169
Family Practice	PCP Instrument	250	1	20/60	83
General Internists	PCP Instrument	250	1	20/60	83
OB/GYNs	PCP Instrument	50	1	20/60	17
Oncologists	Oncology Instrument	550	1	20/60	183
Receptionists & Administrators	Follow-Up Phone Calls	1,103	4	5/60	368
Total		4,236			903

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 Arnold Potosky, PhD, Health Services and Economics, Branch Applied Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, 6130 Executive Blvd., EPN Room 4005, Bethesda, MD 20892–7344 Telephone: (301) 496–5662; *e-mail: potoskya@mail.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: July 21, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison Office, National Institutes of Health.

[FR Doc. E8–17505 Filed 7–30–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request

Evaluation of Risk Factors Associated With Viral Infections in Chinese Donors: a. Risk factors associated with HIV

b. Risk factors associated with Hepatitis B virus (HBV) and Hepatitis C virus (HCV)

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 Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Evaluation of Risk Factors Associated with Viral Infections in Chinese Donors: a. Risk factors associated with Human Immunodeficiency Virus (HIV), b. Risk factors associated with Hepatitis B virus (HBV) and Hepatitis C virus (HCV). This collection will cover two protocols as stated in the title. The first protocol will aim to study risk factors associated with HIV in Chinese donors and the second protocol will study risk factors related to HBV and HCV in Chinese donors. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Understanding the risk factors associated with HIV, HBV and HCV infections in donors is essential for developing donor behavioral screening policies. Injection drug use, sexual transmissions, transfusion history, and medical injections are thought to be major routes of transmission in China but their relative importance in blood donors is unknown.

In the U.S., risk factors have been better characterized but, questions still remain. Risk factors cannot be identified in 33% and 40% of persons with acute hepatitis B and C respectively, and risk factors may differ between the U.S. and China. This study will improve our understanding of potential transfusion transmitted viral risk factors that cannot be optimally studied in the U.S. because of their low prevalence. For example, we may be able to assess whether treatments commonly used in China, such as acupuncture and medical injections, are important routes of HBV and HCV transmission.

The primary objectives of the proposed study are to assess:

- The primary risk factors associated with HIV, HBV and HCV.
- The relative importance of injection drug use, heterosexual transmission, family history, transfusion history, history of previous whole blood or plasma donation, male to male sex, medical injections, acupuncture, and tattoos as routes of transmission for HIV, HBV and HCV.
- Other important routes of transmission for these viruses such as sex with an injection drug user, snorting drugs, living with someone who has HBV and HCV, living with someone who injects drugs, sharing a toothbrush or a razor, having been in jail, occupational history, having surgery, etc.

It is proposed to conduct a large, multi blood center case-control study to meet the study objectives. Cases for the HIV protocol will be donors with confirmed anti-HIV antibody reactivity. Blood Centers will select a random group of donors with negative infectious disease test results as Controls for this study. Controls will be enrolled with a 2:1 ratio to Cases and will be matched to the Cases by blood center and donation month. Blood Centers will contact potential Controls by phone and/or mail, inviting them to come back to participate in this study. Cases and Controls will be consented and interviewed using the same Risk Factor Questionnaire (RFQ) by Chinese-CDC (C–CDC) or blood center staff, either at the local C–CDC or blood center.

The second protocol assessing risk factors related to HBV and HCV will have three groups of donors: ''HBV Group'': HBV (HBsAg) positive donors either from prescreening (rapid testing) or routine screening testing. Confirmatory testing for HBV will be done for these donors. ''HCV Group'': HCV (anti-HCV) positive donors from routine screening testing (blood centers do not do prescreening rapid testing for anti-HCV). Confirmatory testing for HCV will be done for these donors. The third group will be a ''Control Group'' including donors with negative results for all prescreening and routine screening tests. No additional testing is done for these donors. On a monthly basis, the blood centers will use the confirmatory testing results for HBV and HCV respectively, to generate a list of cases. For that same month, the blood center will generate a list of controls (randomly selected and matched by blood center and month of donation.) The same control group will be used for HBV and HCV cases. Donors in all three groups will be mailed a Risk Factor Survey study packet. The packet will include a study information sheet (discussing the purpose and nature of this study), an informed consent document explaining the voluntary nature, the benefits and risks of this study, a RFQ, a small monetary reward for taking the survey and an envelope with paid postage for the donor to mail their completed questionnaire back to the blood center.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,920; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.33; and *Estimated Total Annual Burden Hours Requested:* 1,293.5. The annualized cost to respondents is estimated at: $1,940.25 (based on $1.50 per hour). According to China's National Bureau of Statistics in 2006, the average annual wage in China is 21,001 Chinese Yuan (or $ 2,958 U.S. dollars based on current exchange rate of 1 U.S. dollar = 7.1). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
HIV Risk factor:			
Case	350	0.33	115.5
Control	700	0.33	231
HBV and HCV Risk factor:			
Case	1,700	0.33	561
Control	1,170	0.33	386
Total	3,920	0.33	1,293.5

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) ways to enhance the quality, utility, and clarity of the information 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 10142, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0075, or e-mail your request to *nemog@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: July 23, 2008.

George Nemo,

Project Officer, NHLBI, National Institutes of Health.

[FR Doc. E8–17528 Filed 7–30–08; 8:45 am]

BILLING CODE 4140–01–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.

Protein-tyrosine Phosphotase Inhibitors as Inhibitors of Human Tyrosyl-DNA Phosphodiesterase (Tdp1) and Methods of Treating Disorders

Description of Technology: Tyrosyl-DNA phosphodiesterase (Tdp1) is an enzyme that repairs topoisomerase I (Top1)-mediated DNA damage induced by chemotherapeutic agents (such as camptothecins) and ubiquitous DNA lesions that interfere with transcription and replication. Tdp1 is a relevant target for anticancer therapies due to its role in repairing Top1-mediated DNA damage and DNA damage associated with DNA strand breaks. Tdp1 inhibitors are expected to be effective in cancer treatment when used in combination with Top1 inhibitors.

The current invention is Me-3,4 dephostatin, and more generally protein-tyrosine phosphatase inhibitors, which is a Tdp1 inhibitor. Me-3,4 dephostatin could potentiate the pharmacological action of Top1 inhibitors.

Applications and Modality

- It is anticipated that Tdp1 inhibitors in association with Top1 inhibitors can have selective activity toward tumor tissues.
- Tdp1 inhibitors may exhibit antitumor activity by themselves because tumors have excess free radicals.

Market

- An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.
- 600,000 deaths caused by cancer in the U.S. in 2006.
- Cancer is the second leading cause of death in the U.S.
- Cancer drug market will likely double to $50 billion in 2010 from $25 billion in 2006.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Yves Pommier (NCI) *et al.*

Relevant Publication: S Antony *et al.* Novel high-throughput electrochemiluminescent assay for identification of human tyrosyl-DNA phosphodiesterase (Tdp1) inhibitors and characterization for furamidine (NSC 305831) as an inhibitor of Tdp1. Nucleic Acid Res. 2007;35(13):4474–4484.

Patent Status: U.S. Provisional Application No. 61/042,706 filed 04 Apr 2008 (HHS Ref. No. E–121–2008/0–US–01).

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov.*

Steroid Derivatives as Inhibitors of Human Tyrosyl-DNA Phosphodiesterase (Tdp1)

Description of Technology: Tyrosyl-DNA phosphodiesterase (Tdp1) is an enzyme that repairs topoisomerase I (Top1)-mediated DNA damage induced by chemotherapeutic agents and ubiquitous DNA lesions that interfere with transcription. The current technology are steroid derivatives that human inhibit Tdp1.

Currently, there are various types of Top1 inhibitors used in chemotherapy, e.g., camptothecin. However, Tdp1 inhibitors are expected to be effective in combination therapy with Top1 inhibitors for the treatment of cancers. Combining Tdp1 inhibitors with Top1 inhibitors would allow Tdp1 to potentiate the antiproliferative activity of Top1 inhibitors. In addition to Tdp1's effect on Top1, Tdp1 inhibitors can also exhibit antitumor activity independently, as tumors are shown to have excess free radicals, and Tdp1 repairs DNA damage by oxygen radicals.

Applications and Modality: It is anticipated that Tdp1 inhibitors in association with Top1 inhibitors can have selective activity toward tumor tissues. Tdp1 inhibitors may exhibit antitumor activity by themselves because tumors have excess free radicals.

Market: 600,000 deaths from cancer related diseases were estimated in 2006. In 2006, cancer drug sales were estimated to be $25 billion.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Yves Pommier *et al.* (NCI).

Patent Status:

- U.S. Provisional Application No. 61/000,430 filed 24 Oct 2007 (HHS Reference No. E–130–2007/1–US–01).
- PCT Application No. PCT/US2008/004541 filed 05 Apr 2008, claiming priority to 05 Apr 2007 (HHS Reference No. E–130–2007/2–PCT–01).

Licensing Status: Available for exclusive and non-exclusive licensing.