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with the manufacturer, the Form FDA 483 that prompted the request for formal dispute resolution would be revised or rescinded.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.

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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