Dated: July 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17566 Filed 7–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0094]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 2008 (73 FR 28484), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0562. The approval expires on July 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: July 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17576 Filed 7–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0047] (formerly Docket No. 2008N–0005)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

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.

DATES: Fax written comments on the collection of information by September 2, 2008.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0563. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice—(OMB Control Number 0910–0563)—Extension

The guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to Current Good Manufacturing Practice (CGMP). Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements, or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance provides procedures that encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs (ORA) and center levels and for requesting review by the dispute resolution (DR) Panel (the DR Panel).

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time-consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms prior to the issuance of Form FDA 483, the manufacturer can formally request DR and can use the formal two-tiered DR process described in the guidance.

Tier-one of the formal DR process involves scientific or technical issues raised by a manufacturer to the ORA and center levels. If a manufacturer disagrees with the tier-one decision, tier two of the formal DR process would then be available for appealing that decision to the DR Panel.

The written request for formal DR to the appropriate ORA unit should be made within 30 days of the completion of an inspection, and should include all supporting documentation and arguments for review, as described below. The written request for formal DR to the DR Panel should be made within 60 days of receipt of the tier-one decision, and should include all supporting documentation and arguments, as described in the following paragraphs.

All requests for formal DR should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier-one DR or a request for tier-two DR;
- Name and address of manufacturer inspected (from Form FDA 483);

• Date of inspection (from Form FDA 483);
• Date the Form FDA 483 issued (from Form FDA 483);
• FEI Number, if available (from Form FDA 483);
• FDA employee names and titles that conducted inspection (from Form FDA 483);
• Office responsible for the inspection, e.g., district office (from Form FDA 483);
• Application number if the inspection was a preapproval inspection;
• Comprehensive statement of each issue to be resolved;
• Identify the observation in dispute;
• Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data;
• State the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of Form FDA 483;
• Identify possible solutions;
• State expected outcome;
• Name, title, telephone and fax number, and e-mail address (as available) of manufacturer contact.

The guidance was part of the FDA initiative ''Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products. The agency formed the Dispute Resolution Working Group comprising representatives from ORA, the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The working group met weekly on issues related to the DR process and met with stakeholders in December 2002 to seek their input.

The guidance was initiated in response to industry's request for a formal DR process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained previously in this document. The guidance also covers the following topics:

• The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.
• Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.
• Public availability of decisions reached during the dispute resolution process to promote consistent application and interpretation of drug quality-related regulations.

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: Based on the number of requests for tier-one and tier-two DR received by FDA since the guidance published in January 2006, FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier-one DR, and that there will be one appeal of these requests to the DR Panel (request for tier-two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR, and approximately 8 hours to prepare and submit each request for a tier-two DR. Table 1 of this document provides an estimate of the annual reporting burden for requests for tier-one and tier-two DRs.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Requests for Tier-One DR	2	1	2	30	60
Requests for Tier-Two DR	1	1	1	8	8
Total					68

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

In the **Federal Register** of January 22, 2008 (73 FR 3729), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one comment in response to the January 22, 2008, **Federal Register** notice. The comment asked 3 questions about the DR process set forth in the guidance.

First, the comment asked how many working days are taken by the ORA and center levels to reach a decision after receipt of a request for tier-one DR.

FDA Response—As explained in Section III.A of the guidance, if the ORA unit agrees with the manufacturer, the ORA unit will issue a written response to the manufacturer within 30 days of receipt of the request, noting its agreement with the manufacturer and resolution of the dispute. If the ORA unit disagrees with the manufacturer, the ORA unit will issue a written response to the manufacturer generally within 30 days of receipt of the request, and if the ORA unit is unable to complete its review of the request and respond within 30 days, the ORA unit will notify the manufacturer, explain the reason for the delay (which may include the need for an additional 30 days for center review), and discuss the time frame for completing the review.

Second, the comment asked how many working days are taken by the DR Panel to reach a decision after receipt of a request for tier-two DR.

FDA Response—As explained in Section III.B of the guidance, if the DR Panel determines that the request is appropriate for review, it will schedule a meeting to discuss the issue within 90 days. If the DR Panel agrees with the manufacturer on the issue, the executive secretary of the DR Panel will issue a written response to the manufacturer within 30 days of the meeting, noting its agreement with the manufacturer and resolution of the dispute. If the DR Panel disagrees with the manufacturer on the issue, the executive secretary of the DR Panel will issue a written response to the manufacturer within 30 days of the meeting, noting its decision on the issue. If the DR Panel determines that the request does not qualify for review, the executive secretary of the DR Panel will notify the manufacturer in writing within 30 days of receipt of the appeal. If FDA is unable to complete its review of the request and respond within 30 days, the executive secretary of the DR Panel will notify the

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