[2] The reporting requirements under §§ 601.27(a), 601.33, 601.34, 601.35, 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a). The reporting requirements under § 600.15(b), 610.11(g)(2); 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(d) are included in the estimate under § 601.12(b). The reporting requirement under §§ 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) is also included in the estimate under § 601.12(c). The reporting requirements under §§ 640.70(a), 640.74(b)(3) and (b)(4); 640.84(a) and (c); 640.94(a), 660.2(c), 660.28(a) and (b); 660.35(a), (c) through (g), and (i) through (m); 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.62.

Under Table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
601.91(b)(2)(iii)	1	1	1	1	1

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

Dated: March 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5026 Filed 3–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on 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 April 14, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

FDA previously issued this proposed collection of information in the **Federal Register** of January 26, 2005 (70 FR 3712). On February 24, 2005 (70 FR 9083), FDA withdrew the proposed collection of information to correct the title from ''Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice'' to ''Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.''

Title: Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

Description: 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 practices (CGMPs). 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 will 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 Panel for Scientific and Technical Issues Related to Pharmaceutical CGMP (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 the FDA 483, the manufacturer can formally request dispute resolution and can use the formal two-tiered dispute resolution process described in the guidance.

Tier-one of the formal dispute resolution 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 dispute resolution process would then be available for appealing that decision to the DR Panel.

If a manufacturer disagrees with the scientific or technical basis for an observation listed by an investigator on an FDA 483, the manufacturer can file a written request for formal dispute resolution with the appropriate ORA unit as described in the guidance. The request for formal dispute resolution should be made within 30 days of the completion of an inspection, and should include all supporting documentation and arguments for review, as described later in this document. If a manufacturer disagrees with the tier-one decision in the formal dispute resolution process, the manufacturer can file a written request for formal dispute resolution by

the DR Panel. The manufacturer should provide the written request for formal dispute resolution and all supporting documentation and arguments, as described in the following paragraphs, to the DR Panel within 60 days of receipt of the tier-one decision.

All requests for formal dispute resolution 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:

1. Cover sheet that clearly identifies the submission as either a request for tier-one dispute resolution or a request for tier-two dispute resolution;
2. Name and address of manufacturer inspected (as listed on Form FDA 483);
3. Date of inspection (as listed on FDA 483);
4. Date the Form FDA 483 issued (from the Form FDA 483);
5. FEI Number, if available (from FDA 483);
6. FDA employee names and titles that conducted inspection (from FDA 483);
7. Office responsible for the inspection, e.g., district office, as listed on the Form FDA 483;
8. Application number if the inspection was a preapproval inspection;
9. 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 dispute resolution that may have occurred before the issuance of the FDA 483.
   - Identify possible solutions.
   - State expected outcome.
10. Name, title, telephone and fax number, and e-mail address (as available) of manufacturer contact.

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

Burden Estimate: FDA has reviewed the total number of informal disputes that currently arise between manufacturers and investigators (and FDA district offices) when a manufacturer disagrees with the scientific or technical basis for an observation listed on a Form FDA 483. FDA estimates that approximately 12 such disputes occur annually. FDA believes that the number of requests for formal dispute resolution under the guidance would be higher because manufacturers have expressed reluctance to dispute with the agency scientific or technical issues raised in an investigation in the absence of a formal mechanism to resolve the dispute. In addition, manufacturers have requested the formal mechanisms in the guidance to facilitate the review of such disagreements. Therefore, FDA estimates that approximately 25 manufacturers will submit approximately 25 requests annually for a tier-one dispute resolution. FDA also estimates that approximately 5 manufacturers will appeal approximately 5 of these requests to the DR Panel (request for tier-two dispute resolution).

Based on the time it currently takes manufacturers to prepare responses to FDA concerning issues raised in a Form FDA 483, FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one dispute resolution and approximately 8 hours to prepare and submit each request for a tier-two dispute resolution.

Based on the methodology and assumptions in the previous paragraphs, table 1 of this document provides an estimate of the annual reporting burden for requests for a tier-one dispute resolution and requests for a tier-two dispute resolution under the guidance.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Requests for Tier-One Dispute Resolution	25	1	25	30	750
Requests for Tier-Two Dispute Resolution	5	1	5	8	40
Total					790

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

In the **Federal Register** of September 5, 2003 (68 FR 52777), FDA announced the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' The document requested comments within 60 days on the information collection estimates. No comments were received on the information collection estimates. This document requests comments on the information collection burden that FDA estimates will result from the final guidance.

The guidance was drafted as 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, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine. The working group met weekly on issues related to the dispute resolution 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 dispute resolution 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 dispute resolution processes, the guidance describes a formal two-tiered dispute resolution process that provides a formal mechanism for requesting

review and decision on issues that arise during inspections:

- Tier-one of the dispute resolution process provides a mechanism to raise scientific or technical issues to the ORA and center levels,
- Tier-two of the dispute resolution process provides a mechanism to raise scientific or technical issues to the agency's DR Panel.

The guidance also covers the following topics:

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

Dated: March 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5027 Filed 3–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0167]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Final Guidance for Industry on Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

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 April 14, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

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.

Title: Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

Description: FDA is issuing a final guidance on the Center for Veterinary Medicine (CVM) process for formally resolving disputes relating to scientific controversies. The final guidance describes procedures for formally appealing such disputes. The final guidance provides information on how the agency intends to interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75 (21 CFR 10.75)). In a final rule issued in the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended § 10.75 to reflect the provisions of FDAMA. This final guidance document outlines the recommended procedures for persons who are applicants for approval of animal drugs or other products regulated by CVM who wish to submit a request for review of a scientific dispute.

The final guidance recommends a procedure whereby applicants first seek review through the supervisory chain of command. If the issue is not resolved at the supervisor's level, the interested person may request in writing that the matter be reviewed at the next higher supervisory level. This process may continue throughout the agency's entire supervisory chain of command through CVM and up to the level of the Commissioner of Food and Drugs (Commissioner). At each level of review (Division, Office Director, Deputy Center Director, and Center Director levels) CVM recommends that the applicant identify the information in the administrative file upon which the request is based. If the appeal contains new information not previously contained in the administrative file, the matter will, in accordance with 21 CFR 10.75(d), be returned to the appropriate lower level in CVM for reevaluation based on that new information. After the applicant has appealed the decision through the supervisory chain of command, they may request review through an ad hoc appeals committee or review by the Veterinary Medicine Advisory Committee (VMAC) in writing to the CVM Ombudsman. If the applicant seeks review by the Ad Hoc Committee, the Chair should provide them the opportunity to submit written arguments to the Committee. The applicant may submit a letter appealing the Ad Hoc Committee's decision to the CVM Director and then to the Commissioner. CVM recommends that persons filing a request for review by VMAC provide the CVM Ombudsman with a concise summary of the scientific issue in dispute, including a summary of the particular FDA action or decision to which the requesting party objects, the results of all efforts that have been made to resolve the dispute to date, and a clear articulated summary of the arguments and relevant data and information.

The information collected will form the basis for resolving the dispute between the requester and FDA. The likely respondents to this collection of information are applicants for approval of animal drugs or other products regulated by CVM who have a scientific dispute with FDA and who request a review of the matter.

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials during any previous efforts to resolve the dispute with the agency. CVM considered the number and substance of similar appeals made to FDA in recent years under Guide 1240.3130 to arrive at numbers reflected in table 1 of this document. Guidance #79 will supercede Guide 1240.3130 and CVM will eliminate the guide from the P & P Manual.

In the **Federal Register** of May 19, 2003 (68 FR 27094), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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