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]

BILLING CODE 4160–01–S

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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Guidance	1	2	2	30	60

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

The use of VMAC for resolving scientific disputes represents a new process for CVM. Although the procedures for requesting dispute resolution by a scientific advisory committee as set forth in the final guidance document are new, CVM estimates that the number of respondents who would submit requests would not increase. The number of hours per respondent (30) encompasses a wide range depending on the dispute involved. The estimate was based on discussions with industry and is an average of hours per respondent.

Dated: March 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5040 Filed 3–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 22, 2005, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation by the Office of Surveillance and Biometrics outlining their responsibility for the review of postmarket study design. The committee will also hear an update on the status of recent devices brought before the committee. The committee will discuss and make recommendations on a premarket notification submission for a coronary proximal anastomosis device. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 7, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 7, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–0450, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 7, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–5039 Filed 3–14–05; 8:45 am]

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, DHHS.

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.

Karyotypic Complexity as a Determinant of Anti-Cancer Drug Activity

Ilan R. Kirsch and Anna V. Roschke (NCI).

U.S. Provisional Patent Application filed 04 Feb 2005 (DHHS Reference No. E–101–2005/0–US–01).

Licensing Contact: Michelle A. Booden; 301/451–7337; *boodenm@mail.nih.gov*.