

requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Appeals of Science-Based Decisions Above the Division Level

Description: FDA is issuing a draft guidance on the CVM process for formally resolving disputes relating to scientific controversies. The draft guidance describes procedures for formally appealing such disputes. The draft guidance provides information on how the agency intends to interpret and apply provisions of the existing regulations regarding internal agency

review of decisions (21 CFR 10.75). In a final rule issued in the **Federal Register** on November 18, 1998 (63 FR 63978), FDA amended § 10.75 to reflect the provisions of FDAMA. This draft guidance document outlines the recommended procedure for persons who are applicants for approval of animal drugs or other products regulated by CVM who wish to submit a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 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 through the agency's entire supervisory chain of command through CVM and to 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 the 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 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 the numbers reflected in table 1. Guidance #79, when finalized, will supercede Guide 1240.3130, and at that time, CVM will eliminate the guide from the P & P Manual.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	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 draft guidance document are new, CVM estimates that the number of respondents who would submit requests would not increase. The number of hours per response (30) encompasses a wide range depending on the dispute involved. This estimate was based on

discussions with industry and is an average of hours per response.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments by August 4, 2003 to ensure adequate consideration in

preparation of the final document. Written comments concerning the information collection requirements must be received by the Dockets Management Branch by July 18, 2003. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets