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Food and Drug Administration

[Docket No. 03D–0167]

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Draft Guidance for Industry on Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#79) entitled "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)." This draft guidance document describes dispute resolution procedures by which sponsors, applicants, or manufacturers of FDA regulated products for animals may request review of science-based decisions. This draft guidance does not address procedures for handling issues associated with FDA's new initiative to enhance pharmaceutical good manufacturing practices (GMP's).

DATES: Submit written or electronic comments on this draft guidance by [*insert date 75 days after publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

Written comments on the information collection requirements must be received by [*insert date 60 days after publication in the* **Federal Register**].

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ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance document.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Marcia Larkins, Center for Veterinary Medicine (HFV–7), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 301–827–4535, e-mail: mlarkins@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: FDA regulations, § 10.75 (21 CFR 10.75), provide a mechanism for any interested person to obtain internal review of any agency decision by raising the matter through the established agency channels of supervision or review for that matter.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115). Section 404 of FDAMA creates new section 562 of the Federal Food, Drug,

and Cosmetic Act (the act) (21 U.S.C. 360bbb–1). Section 562 of the act provides that, if a procedure under which an applicant, sponsor, or manufacturer (applicant) could request a review of a scientific controversy related to human drugs, animal drugs, human biologics, or devices did not already exist, either as a provision in the act or a regulation issued under the act, FDA must, by regulation, establish a procedure under which such an applicant may request a review of the controversy, including review by an appropriate scientific advisory panel or advisory committee.

In the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended § 10.75 to state explicitly that an applicant of a drug (including human drugs, animal drugs, and human biologics) or device may request review of a scientific controversy by an appropriate scientific advisory panel or an advisory committee. In the preamble to the final rule, FDA stated that implementation of this provision would be undertaken by the individual FDA centers and would be described in guidance documents. This draft guidance describes CVM's dispute resolution procedures under section 562 of the act.

CVM Appeals Procedure Guide 1240.3130 (Guide 1240.3130) of the CVM Program Policy and Procedures Manual (P & P Manual) describes CVM's current appeals procedure. Because this guidance predates FDAMA, CVM is revising its procedures. Draft Guidance #79, when finalized, will supercede Guide 1240.3130, and, at that time, CVM will eliminate the guide from the P & P Manual.

This draft guidance document describes CVM's procedures for handling requests for internal review of scientific controversies relating to agency decisions affecting animal drugs or other products regulated by CVM. Incorporated in this document is the dispute resolution procedure set forth

in section 404 of FDAMA. While CVM seeks comments on all aspects of this draft guidance, CVM is particularly interested in the definition of a scientific controversy, standards for granting and denying a request for the review of a scientific controversy by an advisory committee, and the time frames for conducting the review.

II. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's Good Guidance Practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on dispute resolution and the procedures regarding requests for review of scientific controversies relating to decisions affecting animal drugs or other products regulated by CVM. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations. If an applicant wants to discuss an alternative approach, they should contact the FDA staff responsible for implementing the guidance. If the applicant cannot identify the appropriate FDA staff, call 301–827–4535.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or 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 BURDEN[1]

	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 [*insert date 75 days after publication in the* **Federal Register**] 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 [*insert date 60 days after publication in the* **Federal Register**]. 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 Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at http://www.fda.gov/dockets/ecomments. Once on this site, select ~~[insert docket number for this publication]~~ Docket No. 03D-0167 draft guidance for industry on "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by

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the Center for Veterinary Medicine" and follow the directions. Copies of this draft guidance may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: 5/9/03
May 9, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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