

require special accommodations due to a disability, please contact Gail Dapolito 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: May 8, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-12367 Filed 5-16-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0167]

Draft Guidance for Industry on Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#79) entitled "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)." This draft guidance document describes dispute resolution procedures by which sponsors, applicants, or manufacturers of FDA regulated products for animals may request review of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 This draft guidance does not address procedures for handling issues associated with FDA's new initiative to enhance pharmaceutical good manufacturing practices (GMP's).

DATES: Submit written or electronic comments on this draft guidance by August 4, 2003 to ensure their adequate consideration in preparation of the final document.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 July 18, 2003.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855.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Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance document.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 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

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 Docket No. 03D-0167 draft guidance for industry on "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by 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: May 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-12369 Filed 5-16-03; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4920-N-25]

Notice of Proposed Information Collection: Comment Request Real Estate Settlement Procedures Act (RESPA) Disclosures

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: July 18, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or Wayne_Eddins@hud.gov.

FOR FURTHER INFORMATION CONTACT: Ivy Jackson, Acting Director, Office of Interstate Land Sales and Real Estate Settlement Procedures Act, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708-0502 (this is not a toll free number) for copies of the

proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Real Estate Settlement Procedures Act (RESPA) Disclosures.

OMB Control Number, if applicable: 2502-0265.

Description of the need for the information and proposed use: The Real Estate Settlement Procedures Act requires settlement service providers to give homebuyers certain disclosure information at or before settlement and pursuant to the servicing of the loan and escrow account. This includes a Special Information Booklet, a Good Faith Estimate, an Initial Servicing Disclosure, the Form HUD-1 or HUD-1A, and when applicable, an Initial Escrow Account Statement, an Annual Escrow Account Statement, an Escrow Account Disbursement Disclosure, an Affiliated Business Arrangement Disclosure, and a Servicing/Transfer Disclosure.

Agency form numbers, if applicable: HUD-1 and HUD-1A.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The total number of annual burden hours needed to prepare the information is 9,672,400; the number of respondents is estimated to be 20,000 generating approximately 129,980,000 responses annually; these are third party disclosures, the frequency of response is annually for one disclosure and as required for others; and the estimated time per

response varies from 2 minutes to 15 minutes.

Status of the proposed information collection: Revision of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: May 9, 2003.

Sean G. Cassidy,

General Deputy Assistant Secretary for Housing—Deputy Federal Housing Commissioner.

[FR Doc. 03-12374 Filed 5-16-03; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4829-N-26]

Notice of Proposed Information Collection: Comment Request; Federally Assisted Low-Income Housing Drug Elimination Grant Program

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* July 18, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8003, Washington, DC 20410, or Wayne_Eddins@hud.gov.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 6152, Washington, DC 20410; (202) 708-3000 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).