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Guidance for Industry and Reviewers

How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug

FINAL GUIDANCE

This final guidance announces the Center for Veterinary Medicine's (CVM's) policy regarding the circumstances under which CVM intends to not accept for review submissions filed during the investigation of a new animal drug and notify the sponsor that CVM intends not to review the submission.

Comments and suggestions regarding this document should be sent to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fisher's Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the Docket No. 01D-0146.

For questions regarding this guidance document, contact Gail L. Schmerfeld, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-1796, E-mail: gschmer1@cvm.fda.gov

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Center for Veterinary Medicine
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How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug

This final guidance represents the Agency's current thinking on the circumstances under which CVM intends to not accept for review submissions filed during the investigation of a new animal drug and notify the sponsor that the submission will not be reviewed. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Introduction:

CVM's Office of New Animal Drug Evaluation (ONADE) encourages sponsors to submit data, study protocols, or other information for review at the most appropriate and productive times in the drug development process rather than submitting all data at one time in a New Animal Drug Application (NADA). Thus, sponsors may submit data intended to support an application for new animal drug approval during the investigation of the new animal drug to an investigational new animal drug (INAD) file. This final guidance announces CVM's policy regarding the circumstances under which ONADE intends to notify the sponsor that its submission relating to a new animal drug approval (filed to the INAD file) will not be accepted for review and remove the submission from the review queue.

A significant backlog in the number of submissions pending review prompted ONADE to look at its review process. In the interest of improving the efficiency of the review process, ONADE examined the causes of delay. ONADE found that one of the significant inefficient uses of reviewer resources is the number of submissions received by ONADE that require significant additional information or rehabilitation for ONADE to conduct its review. ONADE's practice has been to keep a submission "active" pending the submission of additional information from sponsors.

Instead of keeping deficient submissions "active" pending the submission of additional or revised information, ONADE intends to handle them under the policy set out in this guidance. This policy will permit ONADE to focus on reviewing quality submissions that contain all the information necessary for ONADE to evaluate the submission, thereby facilitating timely review of new animal drug applications.

Refusal to review a submission

Within 60 days of receiving a submission, the reviewer, Team Leader, or designated ONADE staff member should determine whether the submission is acceptable for review, using reasons similar to those for refusing to file an application found in 21 CFR 514.110 for refusing to review a submission. For example, ONADE should not review a submission if on its face the information concerning the required matter is so inadequate that the submission is clearly not reviewable. ONADE should consider a submission to be inadequate if the number or type of errors in a submission or flaws in the development plan cause the person making the appraisal to question the quality of the entire submission and conclude that the submission cannot reasonably be reviewed. [1]

If the person making the appraisal finds that the submission is insufficient on its face or otherwise of unacceptable quality for review, the Division should notify the sponsor by letter of its decision not to accept the submission for review. The letter to the sponsor should state that the submission has not been accepted for review and summarize in detail commensurate with the quality of the submission the reasons the submission has not been accepted for review. The letter also should remind the sponsor that the sponsor may request a meeting with ONADE to discuss why the submission was not accepted for review and how best to proceed with drug development and submission of data. Finally, the letter should inform the sponsor that any resubmission of data or information should go through a thorough review process by the sponsor before it is resubmitted to make sure that all the information is both accurate and complete.

[1] Examples of these types of errors could include missing data sets, missing components in the submission, lack of detail in a study protocol, discrepancies between electronic data sets and the paper copy, conflicting information between sections of the submission, and the absence of important information.