ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

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Director, Regulatory Affairs

June 15, 2001 66 '01 JUN 20 P3:47

Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1061
5630 Fishers Lane
Rockville, Maryland 20852

RE: Docket No. 01D-0146
Draft Guidance for Industry and Reviewers on How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; Availability

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments on the draft guidance for industry and reviewers (#119) entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug."

AHI is the national trade association representing research-based manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. Our licensed member companies produce the vast majority of all such products in the United States, as well as the world market. AHI member companies likely submit the most submissions, and certainly the most complex submissions, to CVM for animal health products. As such, AHI has a tremendous interest in the topic under discussion.

The Center is to be commended for encouraging sponsors of new animal drug applications to submit data, protocols, or other information for review at the most appropriate times in the drug development process rather than submitting all data at one time in a New Animal Drug Application (NADA). This policy, referred to as "phased review," adds a significantly to the efficiency of developing and reviewing applications.

AHI is concerned that the draft guidance will prohibit review of generic protocols in the future. A generic protocol is usually a protocol for multi-location studies, whereby the Sponsor is seeking early input in study design and establishment of study parameters prior to expending effort in identifying such study specifics as study location, animal facilities, and personnel. Prohibition of generic protocol review may cause further delays in the drug approval process and/or increase the costs of study qualification by creating redundancies in monitoring.

01D-0146

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Also, AHI shares the Center's concerns that resources should not be spent on attempting to evaluate poor quality submissions. A sponsor that submits a quality submission should not have to wait in the queue while a reviewer spends an inordinate amount of time reviewing a poor quality submission.

AHI questions, however, whether the poor quality submissions are a significant cause of the current backlog in the Center. The draft guidance states:

> "ONADE currently has a significant backlog in the number of submissions pending review. This prompted ONADE to look at its review process. 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 in order for ONADE to complete its review. ONADE's practice has been to keep a submission "active" pending the submission of additional information from sponsors."

We have great interest in the results of the review process that led to the conclusion 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 in order for ONADE to complete its review." AHI has requested a copy of ONADE's review by an FOI request under a separate cover letter.

The problem that the Center attributes to poor quality submissions, according to AHI members, is in part the variation in format and content of applications as required by individual reviewers. In a May 19, 1998 letter to Dr. Andrew Beaulieu, AHI submitted a guidance document entitled, "INAD Phased Review/NADA Technical Section Formats." This document was developed by representatives from member companies of AHI as well as their collaborators and advisors. As stated in the guidance document, the purpose of was to provide a suggested format for the preparation of technical sections in submissions to an INAD file and original and supplemental NADAs. AHI members spent a considerable amount of time preparing this document for the Center's consideration. The standardization of format and content of an application would significantly improve the quality of submissions for new animal drug applications. AHI never received a response to our letter nor our efforts. In addition to developing guidance on deficient submissions, AHI suggests that CVM reconsider developing guidance on the format and content of submissions. AHI is willing to work with the Center to develop such guidance and improve the quality of submissions to the Center.

Respectfully submitted,

Sandra L. Phelan

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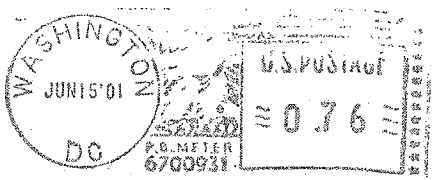

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