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May 30, 2001

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fisher's Lane Rm. 1061
Rockville, MD 20852

Docket Number: 01D-0146, Draft Guidance Number 119, "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation if a New Animal Drug."

To Whom It May Concern:

Novartis Animal Health has reviewed the above-referenced docket, Draft Guidance Number 119, "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation if a New Animal Drug." We have the following comments and suggestions:

1. The Draft Guidance refers to minor and significant deficiencies in a submission, but fails to define those terms. We request that the Center define those terms in the revisions to this draft. For example, numerous minor protocol deviations which do not impact study outcome would be not be considered cause for rejecting a submission, while failure to provide pivotal data for more than ___% of cases enrolled would be cause to reject the submission.
2. The Draft guidance refers to the finding of flaws in the development plan as a reason for a reviewer to reject a submission. We request wording in the Guidance confirming that adherence to a Development Plan which has previously negotiated (and perhaps amended) with the Center as under proposed rule 21 CFR 514.3 will prevent the rejection of a submission for a "flawed" development plan. This will provide industry with assurance that the Center will adhere to previous agreements made with the Sponsor.
3. Please define the time impact of an amendment to a submission requested by the Center in response to minor deficiencies in a submission. The amendment should not restart the 180-day review clock for the submission. When the Sponsor submits the additional information the submission's review should be continued. The Center is already so far behind in its reviews that further resetting of the review clock will cause undue burdens upon industry.
4. Please clarify whether, in the case of resubmission of rejected submissions, the entire data package would have to be resubmitted, or only that information which would be new to the Center. Re-sending large volumes of information which the Center has already received wastes unnecessary time and paper in the submission and review process.

Thank you for the opportunity to comment on this proposed rule. If there are any questions, please feel free to contact me at 1-800-447-2391 ext. 1121.

Sincerely,

Marne L. Platt, VMD
Regulatory Affairs Manager

01D-0146

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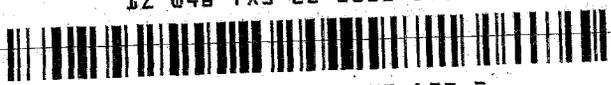
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