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October 27, 2000

Dockets Management Branch
HFV-305, Room 1061
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

SUBJECT: Comments on Proposed Rule 21 CFR 514, Regarding The Procedures for Requesting and Conducting a Presubmission Conference, Docket No. 00N-1399

To Whom It May Concern :

Novartis Animal Health US, Inc. hereby submits comments to the proposed rule, 21 CFR 514.3, new regulations governing the request and conduction of presubmission conferences, as published in the Federal Register on August 25, 2000. Comments are listed below.

1. It is noted in proposed 514.5(f) that although a 30 day response time for industry to address CVM's written memorandum of conference is given, there is no specified time frame for CVM to produce the memorandum of conference. Past experience indicates that Memoranda of Conference, while currently required to be produced within 50 days, may not be received for several months. This dramatically limits the ability of the Sponsor to proceed with the development of the drug, as written agreement on the development plan must be achieved before it is wise to move forward. Including this limit in the regulations will help to prevent such delays. Novartis Animal Health proposes a 25 day response time from the date of the conference for the Center to provide the written Memorandum of Conference and Presubmission Conference Agreement (separately or together) to the Sponsor. The 25-day time frame is consistent with that included in the proposed regulation for FDA to provide written justification for requiring more than one field study for a particular new animal drug.
2. We note that the Sponsor is given 30 days to respond in writing to the Center's Memorandum of Conference and Presubmission Conference Agreement, but again, no time frame is given in which the Center must respond to the Sponsor's comments. We again propose a 25 day response time, calculated from the date of receipt of the Sponsor's comments.

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3. We note in the comments accompanying the proposed rule ("Documenting a Presubmission Conference") that time frames will be included in the Presubmission Conference Agreement, but that no guidance on the duration of those timeframes is given. While we agree that the state of scientific knowledge may change over long periods of time, we are concerned that no proposals regarding the definition of reasonable period of time have been shared with industry. The logistical issues surround the conduct of studies and the drug development process may cause unforeseen delays. We propose that FDA and industry (perhaps through a public meeting or via the Animal Health Institute) discuss what timeframe may be reasonable for the duration of an agreement between the Center and the Sponsor.

4. We note that the proposed regulation states that the entire Presubmission Conference Agreement is no longer binding if the Sponsor fails to abide by any individual portion of that agreement. We feel strongly that this is too restrictive a clause, and that each component of the Presubmission Conference agreement should be judged upon its own merits. There are too many potential reasons for a Sponsor to deviate from any individual portion of an agreement to make this rule realistic or fair. Should an unexpected deviation from one portion of Presubmission Conference Agreement occur during the course of drug development, we propose that other components that are not affected by that change should not automatically be invalidated.

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.

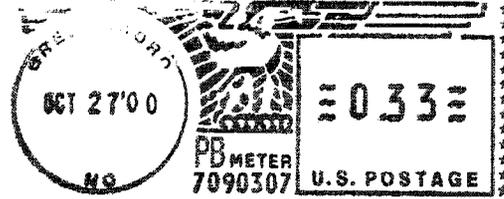
Sincerely

A handwritten signature in black ink, appearing to read 'Marne L. Platt', written over a printed name and title.

Marne L. Platt, VMD
Regulatory Affairs Manager

 **NOVARTIS**

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