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December 8, 2000

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

Re: Docket No. 00N-1399 – Presubmission Conferences

The Coalition for Animal Health is comprised of the major national trade associations representing the animal production and related industries. The Coalition includes general farm organizations, the feed industry, livestock and poultry producer groups, animal health product manufacturers and veterinary medicine practitioners. The Coalition submits these comments in response to the Notice of Proposed Rulemaking published in the Federal Register on August 25, 2000, 65 Fed. Reg. 51782, concerning the regulations necessary to describe the procedures to be followed for requesting, conducting, and documenting presubmission conferences as required by the Animal Drug Availability Act of 1996 (Pub. L. 104-250) (the “Act” or “ADAA”), § 512(b)(3) of the Act (21 USC 360b(b)(3), as amended by section 2(d) of the ADAA.

The Coalition participated directly in the negotiations and legislative effort that resulted in the passage of the ADAA. As a result, the Coalition and its individual members have direct knowledge of the intent of the legislation and is in an excellent

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position to evaluate the extent to which regulations implementing the ADAA embody the spirit of agreements reached with CVM. It is unfortunate that the Coalition is forced to conclude that the intent of the ADAA, with the notable exception of combination drug approvals, is not manifested in either the regulations proposed by CVM or in the manner in which CVM is administering the approval process. We believe that CVM has failed to follow the intent and letter of the ADAA and to act in a manner consistent with commitments made to the Coalition and to Congress during the negotiations for ADAA. In short, the changes in culture at CVM necessary to make the promise of ADAA a reality have not taken place. The following specific comments indicate areas where the regulations fail to embrace the agreements embodied in ADAA.

I. Scope of Presubmission Conferences

Presubmission conferences as described in the ADAA were intended to fundamentally change the manner in which the agency operated and eliminate the constantly moving targets that plagued the approval process. The ADAA requires the agency to make binding agreements regarding **submissions or investigational requirements** with applicants early in the development process. Furthermore the Food, Drug, and Cosmetic Act provides that any conferences prior to submission of an application, where agreement is reached between the applicant and the Secretary of Health and Human Services (the “Secretary”), shall be binding. The regulations should make it absolutely clear that the sponsor should be able to determine, with certainty,

through a presubmission conference all the studies necessary to establish the human safety, animal safety and the efficacy of the product.

II. Advance Information

We are concerned that proposed rule 514.5(d) – Advance Information, will not meet the stated intent of the presubmission conference. We believe that it is unlikely that the drug sponsor will have at a time prior to the presubmission conference the information set forth in the proposed regulation. Rather than requiring all information be submitted prior to the meeting, we suggest that background materials to acquaint participants with information that will be discussed should be sufficient. A presubmission conference is intended to present the sponsor's vision of a development plan, rather than being a full data presentation. If the applicant fails to provide sufficient information for a productive dialogue, then their chances of reaching an agreement acceptable to the Secretary will be limited.

III. Memorandum of Conference

Section 514.5(f)(1) places no timeframe within which the agency must provide a written memorandum of conference. We believe this is a problem given the fact that a primary objective of ADAA was to provide time certainty whenever possible and the Coalition has reliable reports that the agency currently takes over four months to prepare memoranda of conferences, which is unacceptable and clearly violates the intent of

ADAA. Since the agency is required provide the justification for more than one field study in 25 days the agency should also be required to provide the memorandum of conference within 25 calendar days of the meeting.

IV. Field Studies

Section 514.4(f)(2) on field studies is an area where the agency has significantly abused the intent of Congress and all parties participating in the negotiation of the ADAA. The agency has misconstrued the intent of the Act and is attempting to circumvent it through these proposed rules. The default position of the Act is that if a field study is necessary, only a single one is required. In fact, if the agency determines that more than a single field study is necessary, the Act requires the Secretary to provide a written order setting forth the scientific justification for additional studies. Therefore, under the statute, the agency can only require more than a single study where it is **essential** to demonstrating substantial evidence of effectiveness for the intended uses of the drug.

FDA is circumventing the Act by indicating that it may require a “single study in multiple locations.” The agency has misinterpreted the Act – and disregarded its leadership’s statements at every meeting it had with Congress or the Coalition prior to the bill’s enactment – by indicating that a single protocol used in multiple geographic regions is a “single study.” This negates the statutory requirement that the agency provide a written order with scientific justification as to why more than a single study is essential to

demonstrating substantial evidence of effectiveness. There is no mistaking the fact that a requirement by FDA for an applicant to run a study at more than one location is a requirement to have more than one field study.

V. Binding Agreements

The Act provides that agreements regarding submission or investigation requirements reached at a presubmission conference **shall** bind the Secretary and the applicant or requester except in two specific situations. The agency now proposes to allow itself to void a presubmission conference agreement if the sponsor fails to meet timeframes specified in the agreement. Interestingly, it rejects the notion of applying timeframes or corresponding penalties to itself. The Act does not provide the agency with the authority to create additional situations in which agreements are no longer binding, and the congressional reports accompanying the bill's passage make it clear Congress did not contemplate granting such authority to the agency. Therefore the provisions set forth in proposed rule 514.5(h) are outside of the statutory authority of the agency, and we are confident any court would agree with our contention.

We appreciate the opportunity to submit foregoing comments to the docket. We believe the concerns raised by the Coalition are serious and are justified based on the intent of the ADAA and the agreements reached during the good faith negotiations leading up to the passage of the bill by Congress. If FDA is serious about making the

ADA work as intended they will make significant changes prior to finalizing the proposed regulation.

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