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President and CEO

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July 23, 2003

Dockets Management Branch
U.S. Food and Drug Administration
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 03D-0167

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to the Draft Guidance for Industry #79 on “Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine,” published by FDA in the *Federal Register* on Monday, May 19, 2003.

AHI is the national trade association representing 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.

AHI commends the Agency for articulating its dispute resolution process into a concise guidance document. Although the document is well written and generally easy to follow, we feel that the addition of a “flow chart” to graphically illustrate the process will greatly enhance the document to make it more user-friendly. In addition we provide the enclosed comments for your consideration.

Sincerely,



Alexander S. Mathews

Enclosure

03D-0167

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Comment Form

				Date July 23, 2003	Document GFI #79 Dispute Resolution Procedures for Science-Based Decisions on products Regulated by CVM
Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
AHI Comment 1	III.	New D	Insertion of an additional example "D. CVM and an applicant have different interpretation of results/data."	This is one of the more common areas of disagreement between the Agency and the applicant	
AHI Comment 2	IV A 1.b		The time frames and subsequent related submission time frames should be clarified	If new information is provided in the appeal to the Division Director, does this constitute a new "submission?" If so, is this new submission subject to the corresponding submission review time frames? (e.g 180 days)	
AHI Comment 3	IV.A 1 c.i, IV.A 1 c.ii			The guidance document indicates that the Division Director will communicate the Office Director's decision to the applicant What controls will be put in place to insure that the Division Director's letter to the applicant reflects the Office Director's decision?	
AHI Comment 4	IV.A.1.b ; IV.A 1.c.ii.; IV.A.2.c ; IV.A 2.d.		Throughout the document each time an Agency decision is provided to the applicant, the reasons/rationale for the decision should also be provided. This could be accomplished by inserting the following sentence at the appropriate locations within the document: "The response should include the reasoning/rationale for the Agency's decision."	We commonly assume that when the Agency provides a negative decision, they will also provide their reasons/rationale. However, the draft guidance document does not currently require that the reasons/rationale be provided	
AHI Comment 5	New		Insertion of a "Flow Chart" to present the appeals process graphically	Clarification of the appeals process.	