ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

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President and CEO

March 3, 2003

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

RE: Docket No. 02D-0449
Draft Guidance for Industry: The Administrative New Animal Drug Application Process; Availability

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments on the draft guidance for industry (#132) titled "The Administrative New Animal Drug Application Process."

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 commends the Center for recognizing the need to clarify the process for the submission of an Administrative New Animal Drug Application.

We have attached a table outlining our proposed changes to the draft guidance along with the rationale for these changes. Additionally, we have included a illustrative flow diagram of the phased review process and Administrative NADA approval.

AHI appreciates the opportunity to comment on this draft guidance document. Please do not hesitate to contact us if you have questions on our comments or seek additional information.

Sincerely,

Alexander S. Mathews

Enclosures

02D-0449

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AHI Comments to CVM Draft Guidance for Industry

Date. March 3, 2003	FDA Document. GFI #132 The Administrative New Animal Drug Application Process

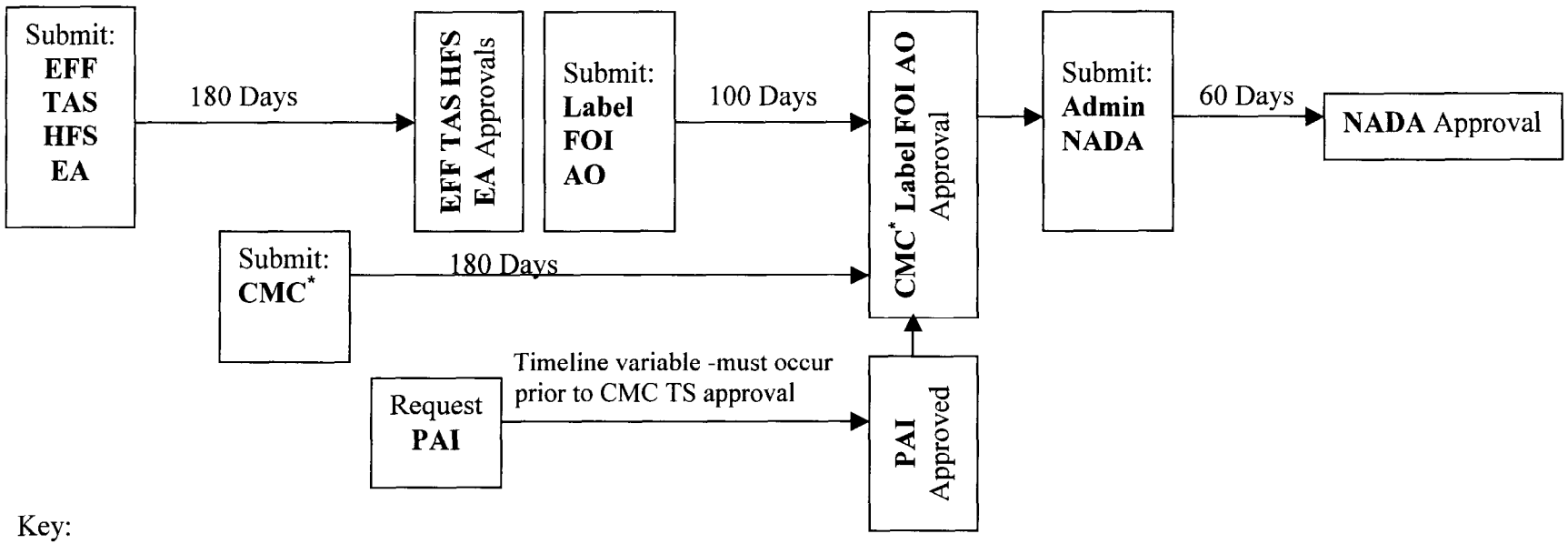
Commenter Name	Comment Number	Clause/ Subclause	Paragraph Figure/ Table Line No.	Type of comment (General/ Technical/Editorial)	COMMENTS	Proposed change
AHI	1	III. Phased Review	D(6) Labelling and D(7) FOI Summary/ pg 5	Technical	We are concerned that the process as currently outlined in the GFI will result in the demise of the Administrative NADA, because of the additional Technical Sections for Labelling and FOI Summary Labelling and FOI Summary as Technical Sections have the potential to add time unnecessarily to the review process, such that Admin NADAs are no longer a viable option.	We suggest that the Labelling, FOI, and All Other Information technical sections be submitted before the sponsor has received the last major (rate limiting) section complete letter. The review time for each of these sections should not be more than 100 days and STARs should be amended to reflect this. [An example of this concept can be seen from the attached flow diagram.] We need to emphases that the sponsor needs to be able to time their submissions to minimize total elapsed time to approval.
AHI	2			General	The need for a primary reviewer to shepherd the entire review process is a critical success factor for implementation of this proposed review procedure (Individual Technical Section reviews then broad-based review of Label, FOI Technical Section).	We suggest the primary reviewer of the Efficacy and/or Target Animal Safety Technical Sections be the primary reviewer of the Administrative NADA.

Commenter Name	Comment Number	Clause/ Subclause	Paragraph Figure/ Table Line No.	Type of comment (General/ Technical/Editorial)	COMMENTS	Proposed change
AHI	3	Title I Purpose	Title line/ pg 2	General/ Editorial	It is not clear that the Administrative NADA itself should be described as a process. The document concerns the entire phased NADA review process, of which the Administrative NADA is the final step	Change the title to The Phased NADA Review Process OR The Phased NADA Review and Administrative NADA Process
			Purpose, pg 2		The purpose should be expanded to include the phased review process.	Reword the purpose to include phased review, e.g.· This guidance defines what the "Phased NADA Review" process and an "Administrative New Animal Drug Application" are, describes the procedures that should be followed if a sponsor exercises the option to use the phased review process and elects to submit an Administrative NADA, and indicates the intended time frames for review of technical information and Administrative NADAs.
		III Admin NADA process/ pg 3	Heading line/ pg 3		The section heading should include the phased review process.	Change the heading to. The Phased Review process or the Phased Review and Administrative NADA process
			Definition/ pg 3		Add a definition of Phased NADA Review.	Definition. Phased NADA Review is a voluntary process in which review of the individual NADA components/ subcomponents is completed during the investigational stage of new animal drug development. The Administrative NADA concludes this process.
AHI	4	III. Phased Review	Definition	Technical	The definition of an Administrative NADA needs to be expanded to include supplements.	"An 'Administrative NADA' is a new animal drug application or a supplemental NADA that is submitted..."
AHI	5	III. Phased Review	D(1) CMC / pg 4	General	It is our understanding that a successful PAI is required prior to issuance of a CMC Technical Complete Letter.	We acknowledge that a successful PAI is required before the CMC TS can be approved. However, we do not believe that a CMC TS should be incompleted based solely on the absence of a PAI inspection We request that the guidance document require that the PAI be requested in time to correspond with the timeline associated with the CMC TS approval.

Commenter Name	Comment Number	Clause/ Subclause	Paragraph Figure/ Table Line No.	Type of comment (General/ Technical/Editonal)	COMMENTS	Proposed change
AHI	6	III Phased Review	D(8) All Other Information/ pg 5	Technical	The definition is unclear as to the timing of when such information is to be submitted and this information is already included in other Technical Sections. The Agency needs to clarify their expectation that this section will contain only new information that was not submitted previously in another technical section. This is in contrast to the Labelling and FOI technical sections, which integrate previously submitted information. The distinction should be stated.	We suggest the following wording for the first sentence of D(8) The **All Other Information** section must include all other information, not previously included in any of the other technical sections, that is pertinent to an evaluation of the safety or effectiveness of the new animal drug for which approval is sought
AHI	7	IV. Submitting an Admin NADA	Pg 6	General	Section IV should be expanded to better define the components of the Administrative NADA. Specifically, additional detail regarding the actual content of the Administrative NADA Summary beyond that described on the FDA Form 356-V would be helpful Additionally, the number of facsimile labels should be stated and Supplemental Administrative NADAs should be included. To ensure consistency within ONADE, we recommend the Policy and Procedures Manual be update to include appropriate SOPs.	
AHI	8	V. Time Frame for Review	Paragraph 3, line 2/ Pg 7	General	Change the word "intends" to "will"	"it will assign a 60-day.. . .

Phased Review Process and Administrative NADA Approval Per Guidance Document #132

EXAMPLE FLOW DIAGRAM



Key:
EFF = Efficacy Technical Section
TAS = Target Animal Safety Technical Section
HFS = Human Food Safety Technical Section
EA = Environmental Assessment Technical Section
CMC = Chemistry, Manufacturing & Control Technical Section
Label = Labeling Technical Section
FOI = Freedom of Information Technical Section
AO = All Other Technical Section
PAI = Pre-Approval Inspection
Admin NADA = Administrative New Animal Drug Application

* Or other rate-limiting Technical Section on critical path