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ANIMAL HEALTH
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27 February 2003

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

Re: Comments to FDA Docket No. 02D-0449, Draft Guidance for Industry #132 "Draft Guidance for Industry: The Administrative New Animal Drug Application Process"

Dear Dockets Manager:

The purpose of this document is to provide Pharmacia and Upjohn (P&U) Animal Health comments on FDA Docket No. 02D-0449, Draft Guidance for Industry #132 "Draft Guidance for Industry: The Administrative New Animal Drug Application Process."

In a meeting 30 January 2003, P&U met with CVM, Office of New Animal Drug Evaluation Director, Dr. Vaughn, and a number of his staff to discuss Guidance 132. During this meeting, P&U had questions on four distinct areas within Guidance 132. P&U provided specific comments and questions on the three newly proposed Technical Sections (TS): Labeling, FOI, and "All Other Information" and we sought clarification on the Chemistry Manufacturing Control (CMC) TS review process and associated pre-approval inspections of commercial manufacturing sites. For this letter, P&U identifies the specific topic and provides our understanding of the new guidance followed by questions and comments for each topic.

Labeling: It is P&U's understanding that the sponsor will continue to create label language and submit relevant label wording with an individual TS (TAS, HFS, EFF). CVM will continue to provide comments via TS complete/incomplete letters and informal communication. CVM's acceptance of labeling (within an individual TS) represents closure on scientific/technical conclusions and language. The sponsor will submit final product label (FPL) in the new Labeling TS, to be filed approximately 100 days prior to predicted "approval" of the last TS (TAS, EFF, HFS, CMC). The focus of the label TS review is insurance of overall Agency consistency, format, organization and appearance. P&U has the following questions regarding the Labeling TS:

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1. Will the sponsor continue to have the ability to use informal communications with CVM to resolve minor labeling issues (e.g., format, typos) prior to final submission? These informal interactions help to minimize multiple review cycles and decrease final review times.
2. Is there an established standard for FPL that CVM reviewers use to determine whether the Labeling TS is complete?
3. When the sponsor receives the Labeling TS complete letter, has S&C and QA completed their review of the label and, if so, what additional review of these items is needed with the Administrative NADA? Will CVM provide detailed written comments on draft label language with each TS complete letter?
4. Has CVM considered adopting electronic label review as proposed by CDER/CBER (Docket 00N-1652) to increase efficiency?

FOI Technical Section: P&U notes that the FOI TS follows the same basic process as labeling. The Sponsor submits draft "FOI" summaries with each TS, and CVM "approves" FOI language with TS complete letter. The Sponsor then submits the FOI TS approximately 100 days prior to projected approval of final TS (EFF, TAS, HFS or CMC) approval. P&U has the following questions/comments on the FOI TS.

1. Is there a common understanding within CVM regarding the responsibility and process for finalizing the FOI Summary?
2. At each TS completion, CVM should clearly state in the TS complete letter whether the FOI summaries are acceptable or not.
3. If CVM revised the submitted summaries, CVM should provide these revised summaries to the sponsor with the TS complete letter.
4. Other than assuring content consistency across CVM for the FOI document, what additional FOI review occurs during the Administrative NADA?

All Other Information TS: It is P&U's understanding that this section is submitted late in the INAD process (approximately 90 days prior to anticipated submission of the Administrative NADA). The purpose of this submission is for the sponsor to provide CVM with any new pertinent safety and or effectiveness information not previously submitted to CVM for the specific indication and species under INAD/NADA review. P&U has the following questions about this TS:

1. If there is no additional information, and the sponsor states that all information has been submitted, is this a sufficient response?

CMC TS: Typically, CVM will order a Pre-Approval Inspection (PAI) at the successful completion of the review of the CMC file. Previously, CVM would issue a CMC TS complete letter stating that "the CMC section is complete pending a successful PAI" and this letter was sufficient for submission in the Administrative NADA. Further discussion at the 30 January 2003 meeting changed our understanding. CVM indicated

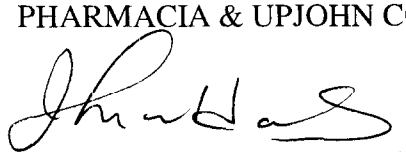
that the sponsor would not receive a CMC TS complete letter until successful completion of the PAI. P&U has the following questions about the CMC TS:

1. When will CVM order the PAI in relationship to the CMC review?
2. Failure to schedule a timely PAI may result in delays for completion of the CMC TS. How will CVM insure timely PAI's?

P&U thanks CVM for creating this new guidance and providing the opportunity for the 30 January 2003 meeting. If CVM has any questions on the comments in this letter, please contact me at (269) 833-2482.

Sincerely,

PHARMACIA & UPJOHN COMPANY



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JWH/cs