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5575 '00 OCT -3

19:36

October 2, 2000

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

Re: **Comments to Docket No. 00D-1418**

Dear Sir / Madam:

Purdue Pharma L.P. has reviewed the draft guidance entitled "Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" and is grateful for the opportunity to provide our comments. Our comments to Docket No. 00D-1418 are provided in Attachment 1. If you have any questions, please do not hesitate to contact me at the number below.

Sincerely,

Irina Privin  
Associate Director  
Regulatory Affairs-CMC  
(203) 588-7485

00D-1418

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Purdue Pharma L.P.

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**Comments to the draft guidance entitled “Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” Docket No. 00D-1418**

In general, the draft document was found to be a well developed guidance. The few comments that were made are provided along with reference to the section and line number.

Section 1.3 (Line 32) – The scope does not include veterinary products.

Section 4.41 (Line 310) – Recommend wording change from “considered” to “maintained”.

Section 4.43 (Lines 317-321) – Eliminate this section, as the wording change in section 4.41 will cover this need.

Section 14.51 (Lines 1333 –1336) – This section should be expanded to provide the API manufacturer with the option of performing an investigation into the returned intermediate or APIs.

The recommended wording is: “ If the conditions under which returned intermediates or APIs have been stored or shipped before or during their return or the condition of their containers casts doubt on their quality, an investigation into the material and the storage and shipping conditions should be conducted on the returned intermediates or APIs. The investigation may conclude that the material should be reprocessed, reworked, or destroyed.”

Section 6.11 (Lines 1373-1375) - Recommend wording change to clarify audit responsibility: “The contract giver should evaluate contract manufacturers (including laboratories) for GMP compliance of the specific operations.”

Section 19.92 (Line1679) – Recommend word change from “records” to “documents”. This clarifies that for API manufacture for clinical study, laboratory notebooks, for example, may be used.

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402