

PHARMACIA

7337 '00 SEP 18 A9:22

September 13, 2000

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

Re: ICH Q3B(R) Impurities in New Drug Products, Step 2 Document
(Docket No. 96D-0005)

Pharmacia Corporation would like to take the opportunity to comment on the referenced document. In general, we find the draft revised document to be a very useful guide and agree with many aspects of it. There are a few areas that we believe need to be modified or clarified. Please find enclosed two copies of our comments for your consideration.

We thank the agency for the opportunity to provide comment.

Respectfully submitted,



Patrick Blacha
Director, Technical Services (Searle)
Pharma Global Quality & Compliance

Attachment

96D-0009

C8

ICH Q3B(R) STEP 2 DOCUMENT
(Docket No. 94D-0005)

Section 2.4 Specification limits for Degradation Products (page 44793)

- In the first paragraph, eighth sentence, modify the sentence “All impurities at a level greater than (>) the reporting threshold should be summed and reported as Total Impurities.”

According to supplementary information provided, “The draft revised guidance addresses only those impurities in drug products classified as degradation products of the active ingredient or reaction products of the active ingredient with an excipient and/or immediate container/closure system.”¹ Therefore, the use of the terminology “impurities” to represent degradation products of the active ingredient or reaction products of the active ingredient with an excipient and/or immediate container/closure system may be inappropriate.

All impurities at the reporting threshold level or greater should be summed and reported as Total Impurities.

Attachment 1, Thresholds for Reporting of Degradation Products in New Drug Products (page 44794)

- For a Maximum Daily Dose of less than or equal to 1 gram (g), the reporting threshold of 0.1 % should be modified.

Although this is not a change from the original guidance document, the reporting threshold level of 0.1 % will continue to be an analytical challenge and may not be consistently achievable for some low dose strength (microgram level) products.

¹ Supplementary Information, page 44792, paragraph seven, second sentence

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Docket No. **96D-0005**

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