

October 6, 2005



Management Dockets, N/A  
Dockets Management Branch  
Food and Drug Administration  
HFA-305  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

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**Re: Docket 2005D-0288**  
**International Conference on Harmonization; Draft Guidance on Q9 Quality Risk Management**

Dear Madam or Sir:

Enclosed please find the specific comments from GlaxoSmithKline for the International Conference on Harmonization Draft Guidance on Q9 Quality Risk Management. These comments are presented for consideration by the FDA. The specific comments are presented in order by section in the draft guidance.

GlaxoSmithKline appreciates the opportunity to provide feedback and suggestions for this draft guidance. I am submitting the comments for this draft guidance by hardcopy. Therefore, you will receive this letter with two copies of comments.

If you have any questions about these provided comments, please do not hesitate to contact me at (919) 483-5857. Thank you for your consideration.

Sincerely,

Mary Faye S. Whisler, Ph.D.  
Assistant Director  
New Submissions, North America

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**Specific Comments:**

1. Introduction

The statement “However, achieving.....on each harm’s occurring and attribute different severities of the harm...” should be changed to “However, achieving.....on each harm occurring and attribute different severities to the harm.”

2. Scope

The statement “This guideline provides.....and examples of tools of quality risk management.....labeling materials.” needs clarification and is too long; therefore it should be changed to: “This guideline provides.....and examples of quality risk management tools ..... all aspects of pharmaceutical quality. This will include development.....and labeling materials.”