



November 11, 2005

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

Re: Docket No. 2005D-0312, Draft Guidance for Industry "**ANDAs: Impurities in Drug Products**"

Pfizer would like to acknowledge the effort put forth by the FDA in the publication of the Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information, August 2005. The guidance is concise, usefully constructed, and refer to other guidance for clarity, under II. Background (lines 47-71). The draft, however, needs editing to be more consistent with other FDA and ICH guidelines. For example, the use of the word "may" should be replaced by "can".

Pfizer appreciates the opportunity to provide the attached comments to further clarify and strengthen the proposed guideline.

Sincerely,

A handwritten signature in black ink that reads "Kieran Dignam".

Kieran Dignam, Ph.D.  
Research Fellow  
Regulatory CMC/QA  
Worldwide Pharmaceutical Sciences  
Pfizer Inc.

A handwritten signature in black ink that reads "Maria Guazzaroni Jacobs".

Maria Guazzaroni Jacobs, Ph.D.  
Director/Team Leader  
Regulatory Monitoring  
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