



March 4, 2004

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

**Re: Docket No. 2003D-0493, Draft Guidance for Industry: Powder Blends and Finished Dosage Units-Stratified In-Process Dosage Unit Sampling and Assessment**

Pfizer would like to acknowledge the effort put forth by the FDA in the publication of the Draft Guidance for Industry on Powder Blends and Finished Dosage Units-Stratified In-Process Dosage Unit Sampling and Assessment. We would also like to acknowledge the acceptance by the agency of the PQRI recommendations. It is recognized that a great effort has been made to incorporate the draft recommendations of the Blend Uniformity Working Group (BUWG) published in the *PDA Journal of Pharmaceutical Science and Technology* 57:59-74, 2003.

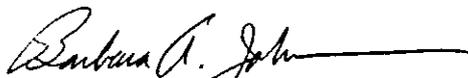
As a member of PhRMA, Pfizer has contributed to the preparation of the industry comments submitted by PhRMA to the agency. In addition to those comments we would like to submit the following five items listed in the table below.

Section	Guidance Line	Comment	Rationale
IV. B.	150-152	Add a reference to Attachment 1. There should be at least 7 samples taken from each of these locations for a total minimum of at least 140 samples. (See Attachment 1.)	Without the attachment, it implies that 140 samples must be tested.
V.		Clarify whether blend uniformity testing and in-process dosage unit testing is required for all BE/biobatches or only for the full-scale validation batches or only for batches that support implementing the stratified sampling method.	
General Comment		Indicate if this guidance is applicable to other unit operations that occur before tableting or encapsulation, for example fluidized bed bead or granule coating, which is immediately followed by encapsulation.	A fluidized bed process can provide mixing such that a subsequent conventional blending step is not required.

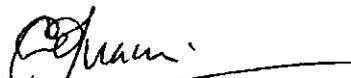
<b>Section</b>	<b>Guidance Line</b>	<b>Comment</b>	<b>Rationale</b>
Glossary	459-460	Provide a better definition of "exhibit batch".	Exhibit batches need to be clarified for NDA applicants.
General Comment		Indicate that this guidance is not intended for PAT method use.	The regimen described in this guidance is not designed for PAT methods.

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

Sincerely,



Barbara A. Johnson, Ph.D.  
Associate Research Fellow  
Pharmaceutical R&D  
PGRD  
Pfizer Inc



Maria Guazzaroni, Ph.D.  
Director/Team Leader  
Regulatory Monitoring  
Quality Operations  
Pfizer Inc