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December 3, 2004

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

Re: Docket No. 2004D-0431, Draft Guidance for Industry and the Food and Drug Administration on Current Good Manufacturing Practice for Combination Products

Pfizer would like to acknowledge the effort put forth by the FDA in the publication of the **Draft Guidance for Industry and FDA on Current Good Manufacturing Practice for Combination Products**. Pfizer appreciates the opportunity to provide comments and have done so through PhRMA. In addition, we are pleased to provide the following comments to further clarify and strengthen the proposed guideline.

Comment 1:
Based on the approaches discussed in the draft guidance, there is a potential to apply a device-centric CAPA approach to drug constituents. In devices, full CAPA expects the analysis of issues to cycle back to the original design authority, especially with any significant adverse events. This analysis usually involves the engineering function. In the drug product area, the analysis typically does not go back to discovery or preclinical groups, rather the adverse event analysis and corrective actions are handled through clinicians and safety analysis. Clarification is needed on how a drug product CAPA application should be conducted to meet FDA expectations.

Comment 2:
On line 192, there is a table that shows additional elements a firm should consider when applying either parts 820 or 211 for combination products. When applying part 211, the table lists design controls, purchasing controls and CAPA, as additional elements. We recommend the list also includes the requirements in subpart 820.20: Management Responsibility, as a new requirement for combination products where the prevalent system is 211.

Comment 3:
Throughout the document, the phrase "during and after joining together" is used to describe the point at which manufacturers must start to consider both Part 820 and Part 210/211. At a manufacturing site, for example, "during...." could be the point at which constituent parts are received and approved for manufacturing, or when the constituent parts are loaded into hoppers on an assembly or packaging line. Clarification is needed regarding the Agency's position on what "during and after joining together" means.

Comment 4:
In order to promote "one FDA decision" from the Agency, we recommend any discussions with Center and Field participants to take place at the same time, by direct communication. In addition, clarification is needed on when discussions with FDA is recommended during development of a combination product.

Comment 5:
Clarification is needed regarding the logistics of inspections at non-domestic sites, the incorporation of ICH guidances into inspections and the mechanics of harmonized inspections.

Comment 6:
Line 221 should read "section II.A" instead of "…I.A" (typographical error).

Sincerely,

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