

Aventis Behring



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February 27, 2004

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

RE: DOCID, fr05se03-69: Federal Register Notice of September 5, 2003 (Volume 68, Number 172, Page 52777-52779);

Comment on Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

Dear Sir:

I am writing on behalf of Aventis Behring, a manufacturer of plasma-derived therapeutic proteins. We respectfully submit the following general comment, suggesting the FDA consider applying the dispute resolution process more broadly than is described in the above-referenced draft Guidance.

We wish to suggest that FDA consider broadening the use of the dispute resolution process to allow its application in the resolution of technical/scientific disagreements that are shared by several sites or multiple pharmaceutical companies. When more than one site/company has received the same 483 observation and/or when an industry practice or approach seems to differ with FDA expectations, it would be useful to be able to apply a formal dispute resolution process to establish what the proper GMP standard should be.

Mechanisms do exist to present differences in approach between industry and FDA, such as the publication of technical reports by industry groups, or the dialog that may take place between industry and FDA during industry-FDA meetings. However, these exchanges are non-binding, may be protracted, and often do not result in resolution of important issues. A more efficient and binding method of resolution is needed when there are legitimate differences between FDA and industry over scientific/technical matters that may affect more than one company.

Consistent with the stated goals of the "GMPs for the 21st Century" initiative, we seek a process to assure science-based/risk-based decision making when both regulatory authorities and industry must interpret GMP regulation/guidance. In order to achieve a common understanding of GMPs in the 21st century, we propose that the dispute resolution process could be applied in these situations by having either a consortia of companies or trade/professional associations present these issues to a dispute resolution panel on behalf of the industry or a sub-set of the industry.

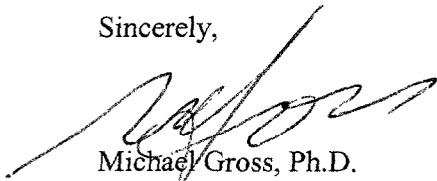
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We request that FDA consider this proposal to expand the application of the Dispute Resolution process to assure that GMP interpretation is founded on sound scientific principles.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Gross", written over the typed name.

Michael Gross, Ph.D.
Vice-President Worldwide Compliance
Aventis Behring