



**asociación española de fabricantes
de productos de química fina**

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD-20852
Estados Unidos, USA

Dear Sirs,

We refer to document "Guidance for Industry: Drug Substance; Chemistry, Manufacturing and Controls Information; Draft Guidance", issued January 5th, 2004.

Please find below our comments:

- The document clearly modifies the requirements included in ICH Q7A, "Note for Guidance Good Manufacturing Practices for Active Pharmaceutical Ingredients", agreed and signed by the Three Regions.
- The draft shows discrepancy in content and extent with ICH M4, "The Common Technical Document".
- Many instructions included in the document, specially Attachment 1 and Attachment 2, are neither scientifically based nor justified.

Our suggestion will be to redraft the entire document taking into account the ICH Guidelines, to respect the efforts already devoted on those subjects by the Governments, the Regulating Bodies and the Industry. If deemed necessary, we can provide a more detailed discussion on some points, and we are willing to collaborate with FDA to improve the guidance.

Sincerely,

Rafael Beaus
AFAQUIM

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