APIC Active Pharmaceutical Ingredients Committee

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Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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Guidance for Industry Comparability Protocols Chemistry, Manufacturing and Controls Information

Dear Sirs,

With regard to above mentioned document, CEFIC/APIC does not find it useful to comment in detail on this draft Guidance, because the key-problem on the submission of changes by dedicated API manufacturers (DMF holders) should be solved first. Currently DMF holders are completely dependent on their (often many) customers' willingness to submit supplements / comparability protocols for their (A)NDAs in which the DMF is referenced. This willingness is invariably very low.

What the API industry needs is a post-approval change authorization system that will grant authorization to implement the change to the API manufacturer itself instead of to its many customers. Within the current system the use of comparability protocols will almost always be out of reach for the API manufacturing industry sector. CEFIC/APIC politely requests further efforts to be taken by FDA to resolve this problem for our industry. Furthermore, we hope for a certain relief in relation to this issue to be obtained from the currently running FDA's CMC Risk Based Review project.

We trust that you will take this matter into consideration and look forward to reading from you very soon.

Yours sincerely,

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