Submitted electronically to *http://www.regulations.gov*

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

May 19, 2014

Re: Submission of Comments to Docket No. FDA-2014-D-0103; Food and Drug Administration; *Draft Guidance for Industry on Analytical Procedures and Methods Validation for Drugs and Biologics*.

The Bulk Pharmaceuticals Task Force (BPTF) wishes to thank the FDA for updating guidance on assembling information and presenting data supporting analytical methodologies.

The BPTF is an affiliate of the Society of Chemical Manufacturers & Affiliates (SOCMA) which is a leading trade association of specialty batch and custom manufacturing chemical industry manufacturers representing more than 2,000 manufacturing sites with over 100,000 employees. The BPTF is an association for manufacturers of APIs, excipients and intermediates whose primary purpose is to seek clarification of the current regulatory requirements for these products and to interact with government agencies on emerging issues that may impact BPTF members.

In general, the BPTF supports the draft guidance made available through a notice published in the Federal Register on February 19, 2014 but in particular wishes to comment on the following items listed using the line numbers provided in the draft guidance document:

Section V Reference Standards and Materials

Current text - Lines 228-231 state the following:

Information supporting reference standards and materials include qualification test protocols, reports, and certificates of analysis (including stability protocols and relevant known impurity profile information, as applicable).

Comment:

It is recommended that this statement be confirmed or that the intent be clarified. Is the agency expecting that such data be submitted as part of the CMC package for reference standards, including compendial reference standards? Currently only a certificate of analysis accompanies a USP Reference Standard.

Section B Analytical Method Comparability Studies; Part 1 Alternative Analytical Procedures

Current text - Lines 420-27 state the following:

You should perform a comparability study that demonstrates at a minimum that:

- The new method coupled with any additional control measures is equal or superior for the original method for the intended purpose.
- The new analytical procedure is not more susceptible to matrix effects than the original procedure.

Comment:

It is recommended that "matrix effects" be defined or that the intent be clarified.

Section B Analytical Method Comparability Studies; Part 2 Analytical Methods Transfer Studies

Current text - Lines 459-461 state the following:

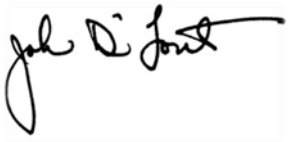
In cases where the transferred analytical procedure is also a stability indicating method, forced degradation samples or samples containing pertinent product-related impurities should be analyzed at both sites.

Comment:

It is recommended that this statement be deleted. The specificity of a method is established during development, not during method transfer. Appropriate system suitability criteria (i.e., resolution) should be provided for methods when needed, and the achievement of the system suitability criteria during the transfer should be adequate to demonstrate a successful transfer of method specificity.

BPTF appreciates the opportunity to submit these comments, and thanks the agency for its attention to our request for clarification and revision.

Sincerely,



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