



PDA Global Headquarters

Bethesda Towers
4350 East West Highway
Suite 200
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

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Editor, *PDA Journal of
Pharmaceutical Science
and Technology*:
Lee Kirsch, PhD
University of Iowa

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

**Ref: International Conference on Harmonisation; Draft Guidance on Q4B
Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria;
Published August 8, 2006 (Docket No. 2006D-0297)**

Dear Sir/Madam

PDA is pleased to provide comments to FDA on ICH Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological and device manufacturing and quality.

The draft guidance provides a procedure to facilitate acceptance by regulatory authorities of Pharmacopeial test methods in the three ICH regions. These test methods are referred to in the draft guidance as "analytical procedures and/or acceptance criteria (APAC)". The draft guidance is intended to facilitate regulatory acceptance of these proposed test methods and their interchangeability with test methods contained in the local regional pharmacopeias, thus avoiding redundant testing and different acceptance criteria in favor of a common testing strategy in each ICH regulatory region. PDA wishes to thank the Agency for the opportunity to provide comments on this document.

PDA's comments were developed by a cross functional team of PDA members, working through our Regulatory Affairs and Quality Committee. We support the general concepts presented in this draft and we believe that this document will help to ensure that harmonization efforts remain a high priority across the regulatory regions and among the USP, JP and Ph. Eur. Our detailed comments are provided in the attached table; however the following list presents some of the major conclusions reached by the PDA review team.

1. The document should provide registration guidance on the appropriate reference for the harmonized procedure. This would ensure consistent referencing that is acceptable by the regulatory authorities for the various geographic regions. Detail regarding regulatory filing implementation must be developed in concert with this guidance either as part of this document or a companion document. The individual Q4B annexes should not move forward until this guidance is available.

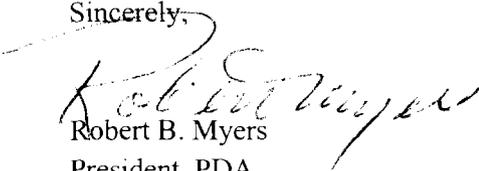
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2. PDA recommends replacing the term “Non-PDG” with the phrase “one or more of the three pharmacopeias that comprise the PDG” through out the document. This would clarify that proposed harmonized text would be proposed from one or more of the PDG members. This phrasing is consistent with the scope and intent of this document.
3. The content of section 2.8 (Pharmacopeial Tests and Acceptance Criteria) of ICH Q6A would need to be updated to agree with the concepts outlined in this draft of Q4B.

If you have any questions regarding our comments, or how we may further assist with the development of the Guidance, please contact me.

Sincerely,



Robert B. Myers
President, PDA

Attachment: Detailed Comments Table