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

Ref: Docket No. 2006D-0297, Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria (RAAPAC)

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the Draft Guidance on Q4B Regulatory acceptance of Analytical Procedures and/or Acceptance Criteria, published on August 8, 2006 in the Federal Register.

Abbott supports the general concepts presented in this draft Q4B guidance document and believes that it will help to ensure that harmonization efforts remain a high priority across the three regulatory regions and among the United States Pharmacopeia, the European Pharmacopoeia and the Japanese Pharmacopoeia.

If this guidance were to be adopted, Section 2.8 (Pharmacopoeial Tests and Acceptance Criteria) of ICH Q6A may need to be updated to recognize the concept that harmonized text can be proposed by one or two but not necessarily all three PDG pharmacopoeias.

We also recommend that this draft document provide more guidance regarding regulatory filing implementation expectations, particularly for text proposed by only one or two of the pharmacopoeias that is accepted by the Expert Working Group as harmonized.

Specific comments pertaining to various sections of the guidance are attached to this letter.

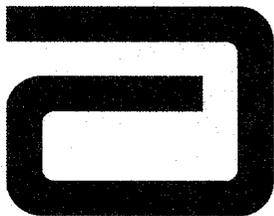
We thank the Food and Drug Administration for consideration of Abbott's comments. Should you have any questions, please contact Kathy Wessberg at (847) 938-1264 or by email, kathy.wessberg@abbott.com.

Sincerely,

Scott Messner

2006D-0297

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Comments on the Guidance Document

Comment on the wording of Section 1.2, Background.

Comment: In line 18, we recommend that the phrase “in each regulatory region” be changed to “across the regulatory regions” to better convey the concept that harmonization aims to facilitate a common testing strategy across the regulatory regions and not within each region.

Comments on the wording of Section 1.3, Scope of the Guideline and Section 3, Glossary

Comment: In line 29, remove “non-PDG” and replace with the phrase, “text proposed from one or more of the three PDG Pharmacopoeias.” The definition of non-PDG text should also be removed from the Glossary in section 3, lines 95 and 96. Also, change the definition of Document Submission in the Glossary to “The working documents received from one or more of the three PDG Pharmacopoeias that contain the proposed APAC and any other support documents provided for Q4B evaluation.” The term non-PDG text lacks clarity when it is introduced in section 1.3. This suggested change allows the reader to readily understand the flexibility desired by the Q4B Expert Working Group.

Comment on the wording of Section 1.4

Comment: In lines 47 and 48, we recommend striking the last sentence starting with “Unilateral Changes/revisions . . .” The concept outlined in the sentence before this one, where the EWG would evaluate the merit of a change and the appropriateness of any subsequent Q4B activity adequately covers the actions that should be taken if a revision to a text occurs. Automatically voiding the ICH status because of any change seems very drastic and in conflict with the concept described in the prior sentence (lines 45, 46, 47).

Comment on Section 2, Guidelines, specifically lines 65-67.

Comment: Section 2.1.3 (Step 3) of the Q4B evaluation process should include a provision to allow the Pharmacopoeia(s) that submitted the harmonization text to review and agree with any revisions made to the annex due to comments received. We suggest that the sentence in line 67 be changed to: The annex can be revised based on comments received, with the agreement of the originating Pharmacopoeia(s).

Comment on the content of the Table in Attachment I

Comment: The note (*per ICH SC, work will just be on “Colour”*) should be removed. We recommend that both the Colour and Clarity tests be harmonized as part of the PDG process.