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**Date:** ► October 9, 2006

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

**Subject:**

***Draft Guidance on Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria***

**Docket No. 2006D-0297**

Dear Sir/Madam:

Amgen is a global biotechnology and pharmaceuticals products company based in Thousand Oaks, CA, which strives to serve patients by transforming the promise of science and biotechnology into therapies that have the power to dramatically improve people's lives.

We are pleased to provide the following comments on the draft guidance, *Draft Guidance on Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria*. We have identified two general concerns that are of primary importance. In addition we have a few specific comments with suggested edits.

**General Comments:**

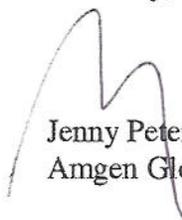
- We recommend replacing the term "Non-PDG" with the phrase "one or more of the three pharmacopeias that comprise the PDG" throughout the document. This would clarify that proposed harmonized text would be proposed from one or more of the PDG members. This phrasing is in synch with the scope and intent of this document.
- In the event that one of the parties disagrees, then we recommend against accepting an individual pharmacopoeia's procedure as harmonized without agreement from the others if "text" only exists in one of the pharmacopoeias, ie, harmonized text should be fully reviewed by all parties. This point should be directly stated in the guidance.

**Specific Comments:**

Section	Line No.	Comment	Edit
1.3	28-29	Reworded for clarity. See bullet point 1 above.	<p>REPLACE: <i>"It also provides... non-PDG text."</i></p> <p>WITH: <i>"It also provides flexibility so that the Q4B EWG can evaluate and regulatory authorities can choose to accept text arising from one or more of PDG members."</i></p>
1.4	44-45	Reworded for clarity	<p>REPLACE: <i>"The EWG should be notified...to the Q4B process."</i></p> <p>WITH: <i>"PDG shall notify EWG of text revisions made, submitted and accepted using the Q4B process."</i></p>
1.4	47-48	The last sentence starting with "Unilateral changes/revisions. . ." should be removed. Lines 44-47 seem to satisfactorily cover the appropriate actions that should be taken if a revision to a text occurs. An automatic voiding of ICH status seems very drastic and in conflict with the text in lines 44-47.	<p>STRIKE: <i>"Unilateral changes/revisions... will void the ICH final status."</i></p>
2.1.3	67	Process clarification.	<p>ADD: <i>"The annex can be revised based on comments received with the agreement and sign-off of the pharmacopeia producing the APAC."</i></p>
Glossary	95-96	The definition for Non-PDG should be eliminated as it is confusing. The PDG is not the PDG if all three of the pharmacopoeias do not agree. Two of the three acting in coalition without the consent of the third pharmacopoeia can not be considered "acting together as the PDG". Please see suggested replacement wording for "non-PDG" in bullet point 1 of the General Comment section above.	<p>STRIKE: <i>"Non-PDG - One or two...Acting together as the PDG."</i></p>

If you have any questions regarding our comments, or how we may assist with further development of this guidance, please contact Jenny Peters at (805)-447-8840.

Sincerely,



Jenny Peters  
Amgen Global Regulatory Affairs & Safety