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Wyeth

October 6, 2006

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2006D–0296, August 8, 2006 (71 FR, 45058-45059)

Dear Sir/Madam:

Wyeth Pharmaceuticals is submitting the following comments on the two draft International Conference on Harmonisation (ICH) guidances entitled, "Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria (RAAPAC)" and "Annex 1: Residue on Ignition/Sulphated Ash General Chapter Analytical Procedures and/or Acceptance Criteria (APAC)."

Wyeth is one of the largest research based pharmaceutical and healthcare products companies and is a leading developer, manufacturer, and marketer of prescription drugs, biopharmaceuticals, vaccines, and over-the-counter medications. Wyeth supports the development of these documents, as we believe they offer valuable guidance to establish standard harmonized analytical methodology and acceptance criteria from a global perspective. Wyeth appreciates the opportunity to comment on the above mentioned draft guidances; our comments on the Q4B RAAPAC guidance are provided below. We have no comments on Annex 1.

General Comment

To achieve the intended result, the ICH Q4B process should be closely aligned with the Pharmacopoeial Discussion Group (PDG) process. The timely availability of the ICH Q4B outcomes is important and where possible should be provided in conjunction with the official adoption dates defined by the three pharmacopoeias. As such, the process described in this guidance moving forward should be closely integrated with the timelines for PDG harmonization efforts.

Wyeth

Section 2.3 Use of the Accepted APAC

This section states, "...When changing to the Step 5 APAC, any change notification and/or prior approval should be handled in accordance with established regional regulatory mechanisms. These regional mechanisms will be described in the topic-specific annexes." We believe this statement implies that compliance with a published APAC would require a regulatory filing. However, if a sponsor already references a current pharmacopoeia, it may not be necessary to amend an approved application should, for example, a certain parameter be defined (such as sample size for Residue on Ignition/Sulphated Ash). Any validation required to implement a new APAC would normally be handled under GMP controls.

We recommend that the statement be revised to "...When changing to the Step 5 APAC, any change notification and/or prior approval (if required)[1] should be handled in accordance with established regional regulatory mechanisms. These regional mechanisms will be described in the topic-specific annexes." Wyeth's suggestion is intended to clarify that compliance with a published APAC may not always require a regulatory filing.

We are submitting the above comments in duplicate. Wyeth appreciates the opportunity to comment on the above mentioned draft guidance and trusts that the Agency will take these comments into consideration.

Sincerely,

Roy J. Baranello, Jr.
Assistant Vice President
Regulatory Policy and Operations
Global Regulatory Affairs

[1] Emphasis added to highlight proposed revision.