



Connecting People, Science and Regulation®

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March 26, 2013

Roger Williams, MD, USP
Chief Executive Officer
U. S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Reference: Volume 39, No. 1; January/February 2013 Pharmacopeial Forum; Proposed In-Process Revision to General Notice Section 5, Monograph Components

Dear Dr. Williams,

The above referenced issue of *Pharmacopeial Forum* contains a proposed change to Section 5.80, *Reference Standards*, to include the following text:

“Where USP or NF tests or assays call for the use of a USP Reference Standard, only those results obtained using the specified USP Reference Standard are conclusive for purposes of demonstrating conformance to such USP or NF standards.”

PDA wishes to offer comments on this proposed change and is pleased to have the opportunity to do so. 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. Our comments were prepared by a committee of experts with experience in pharmaceutical and biopharmaceutical product issues, including members representing our Regulatory Affairs and Quality Advisory Board.

PDA is concerned that this proposed change is not aligned with the long-standing practice between the pharmaceutical industry and the USP for establishing USP Reference Standards. USP Reference Standards are used in analysis of excipients, APIs and drug products and are considered by the industry and regulatory authorities as the highest quality of material available for determining the suitability of these materials. In most cases the Reference Standard material is donated by individual companies within the pharmaceutical industry. The company which donates the Reference Standard material typically donates the same lot of material to other compendia such as the European Pharmacopeia and the Japanese Pharmacopeia, and maintains a record of the lot of material donated which

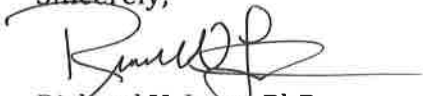
designates the scientific qualification and purity designation for that Reference Standard. The company then uses a portion of the donated Reference Standard lot internally for testing purposes. In other instances, companies will qualify a second standard against the USP Reference Standard. Both of these practices are scientifically justifiable and accepted by global regulatory authorities. This is CGMP. It is also supported by ISO Standards, in particular the ISO 17025 Guide *General Requirements for the Competence of Testing and Calibration Laboratories*. PDA believes the USP should continue to maintain Reference Standards of the highest quality for testing purposes, but should consequently allow the pharmaceutical industry to continue to determine how they will employ the standards in individual companies in accordance with accepted good practices. We recommend this proposed change not be adopted.

We also note that most of the compounds used to establish USP Reference Standards are donated free of charge by the pharmaceutical industry. Many of these Reference Standards are of considerable financial value.

Again, PDA appreciates the opportunity to comment on this proposed change and provides these comments for your consideration. PDA believes that these comments will clarify the need and intent to utilize appropriately qualified Reference Standards in routine use and will better serve the needs of compendial scientists, regulators and industry.

We would be pleased to meet with USP to provide clarification of our comments. Should you wish to pursue that opportunity, or if there are any other questions, please do not hesitate to contact me.

Sincerely,



Richard V. Levy, PhD,
Senior Vice President Scientific and Regulatory Affairs, PDA

CC: Richard Johnson, PDA
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