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USP’s Role in Naming Drugs and Biologics

**Statement by Jaap Venema, Ph.D., Executive Vice President & Chief Science Officer,
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(Rockville, Md., August 28, 2015) “This week, the U.S. Food and Drug Administration (FDA) published a draft guidance and a proposed rule on nonproprietary naming of all biological products. While the U.S. biosimilar approval pathway is still relatively new, the U.S. Pharmacopeial Convention (USP) has been part of a well-established drug naming system, which has included biologics, and our role in setting public standards for quality is well-recognized in Federal law. USP will continue to play these roles as it has since the beginning of drug approval and licensing laws in the U.S.

USP’s mission is to improve global health through public standards that help ensure the quality, safety and benefit of medicines. Public standards that ensure product quality and consistency are a critical part of the overall safety net that protects our medicines and the patients who use them. A public quality standard allows independent determination that a product has been made according to regulatory expectations for identity, strength, quality and purity regardless of a manufacturer or manufacturing process. Ultimately, a public standard assures practitioners and patients that a product is what its label says it is.

USP’s approach to developing standards for drugs and biologics evolves over time as the therapeutic landscape changes. Thus, USP continues to engage appropriate stakeholders, including FDA, in discussions that recognize the transforming nature of therapeutics, the critical role of transparent and science-based public standards for quality, and drug naming systems. USP is currently reviewing FDA’s draft guidance and proposed rule and looks forward to engaging in a dialogue with and providing comments to the Agency.”

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The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP’s standards are used worldwide. For more information about USP, visit <http://www.usp.org>.

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