PDA Global Headquarters
Bethesda Towers,
Suite 600
4350 East West Highway
Bethesda, MD 20814 USA
TEL: +1 (301) 656-5900
FAX: +1 (301) 986-0296

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin
Germany

31 July 2020

Jessica Simpson
Manager, Compendial Operations
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville MD 20852

Re: General Notices revision proposed in *Pharmacopeial Forum* 46(2)

Dear Ms. Simpson:

PDA appreciates the opportunity to comment on the revision to the General Notices proposed in *Pharmacopeial Forum* [*PF*] 46(2), which would add a sentence regarding biologics nomenclature and official titles. We understand that USP published this proposal for a second time to gain updated comments and feedback on this difficult nomenclature topic.

As you know, biologics nomenclature is complex. USP's decisions, while focused on US regulatory policy, would impact products manufactured and marketed around the globe. Because nomenclature affects supply, USP's language in the *General Notices* may impact patient access to important medicines worldwide.

PDA encourages USP to pause use of the *PF*'s formal notice and comment process to advance this issue and to provide clear messages about USP's overall goals and intentions. This would begin a conversation focused on finding answers. USP's conversation with stakeholders could thoroughly consider all the issues involved, including global harmonization.

PDA would be happy to serve as a facilitator for this conversation. Because PDA has not expressed any views on USP's proposed policy, we can help guide the conversation in a thoughtful and productive manner. As a neutral party seeking only continued patient access to high quality products, PDA can convene and guide a workshop or conference of originator and biosimilar manufacturers, regulators, and USP. PDA feels confident that such a conversation would reach a satisfactory result.

Finally, we support USP's continued focus, as expressed in the Briefing, "on developing performance standards, which are applicable to classes of biologics (e.g., monoclonal antibodies or cell therapies), as well as standards for raw materials," rather than monographs. As the Briefing notes, USP has received non-aligned feedback from key stakeholders regarding the development of monographs for biological products. Test methods for quality attributes, in contrast, provide meaningful value to patients and to manufacturers. PDA would be pleased to continue to engage with you in scientific dialogue on standards that would be most helpful and advance our common goals of promoting access to and protecting the quality of biological products.

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 have been prepared by PDA

members with expertise in pharmaceutical, biopharmaceutical, and combination products manufacturing and compendial topics on behalf of PDA's Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard Johnson
President and CEO

cc: Glenn Wright, PDA; Ruth Miller, PDA