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1946
70TH ANNIVERSARY
2016

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March 29, 2016

Desmond Hunt
United States Pharmacopeia
2601 Twinbrook Pkwy,
Rockville, MD 20852

Reference: USP General Chapter Prospectus Documents:
Storage and Transportation of IDPs
Metal Packaging Components and their Materials of Construction

Dear Dr. Hunt:

PDA appreciates that the USP has listened to the feedback of its stakeholders, and has put in place this General Chapter Prospectus pilot process for early input into general chapters. General chapters have such broad reaching impact. This new process will enhance the knowledge base of the Expert Committees, and will hopefully result in chapters with broader industry consensus and buy-in.

With respect specifically to the Prospectus on Storage and Transportation of Investigational Drug Products, PDA believes the creation of this general chapter is superfluous and will cause confusion ultimately resulting in delay in bringing new therapies to the market. This is contrary to ICH Q10 whose first objective is to achieve product realization.

PDA has a concern that USP general chapters cannot be written, revised, and implemented to keep pace with the rate of change in industry and innovation. Creating general chapters such as these runs the risk of inhibiting new practices and product types. Therefore discussions on investigational drug products are best kept between regulators and the companies developing the products.

Clinical Trial Materials are controlled by the regulatory agencies and the companies; covered under GMPs and standards developed by ICH; and do not fit under the remit of the USP. WHO already has regulatory guidance in place to address these issues as do other major regulatory agencies around the globe (e.g. Annex 13 of the EU GMPs). USP's proposed chapter could be misinterpreted as a binding requirement regarding storage and transportation practices. Such requirements do not belong in a pharmacopoeia..

Whereas PDA believes that in the case of the Prospectus on Metal Packaging Components and their Materials of Construction, this fits well within the primary remit of the USP, to develop monographs that ensure safe drugs and supports the development of this general chapter.

PDA would be happy to elaborate further through participation in a teleconference, if such is scheduled, or to set up a meeting discuss this further.
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 manufacturing and pharmacopeia publications including members representing our Board of Directors and our Regulatory Affairs and Quality Advisory Board.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson
President, PDA

CC: Jaap Venema, USP; Richard Levy, PDA; Denyse Baker, PDA