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September 29, 2004

Dr. Claudia Okeke
U.S. Pharmacopeia
12601 Twinbrook Parkway
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Dear Dr. Okeke:

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On behalf of the Steering Committee and the Board of Directors of the Product Quality Research Institute (PQRI), I am pleased to submit the enclosed stimuli article (*Basis for Using Moisture Vapor Transmission Rate Per Unit Product in the Evaluation of Moisture-Barrier Equivalence of Primary Packages for Solid Oral Dosage Forms*) for consideration and publication in the Pharmacopeia Forum.

As you are aware, the Product Quality Research Institute is a unique organization that brings together the innovator and generic pharmaceutical industry, academia and the FDA (specifically the Center for Drug Evaluation and Research) to address issues related to pharmaceutical product quality. In addition to academic and industry members, the Container/Closure Working Group (CCWG) of PQRI included FDA representatives from CDER's Office New Drug Chemistry and Office of Generic Drugs, as well as USP representation. The CCWG has an active project on package equivalence intended to support the FDA's impending PACPAC draft guidance, and also to extend the relevance of the USP General Chapter <671> Containers – Permeation. The enclosed article provides the theoretical basis for the application of Moisture Vapor Transmission Rate per unit (MVTR/unit), and is the basis for the project that will start shortly via an initial pilot/range-finding study.

Going forward, the results of the pilot/range finding study, any further pivotal study, the results of any data-mining activities, and any recommendations for changes to the FDA guidance or the USP General Chapter would require dissemination to a much wider audience.

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The PQRI Steering Committee, of which USP is a long-time member, respectfully requests consideration for publication in the Pharmacopeia Forum Journal, noting that PQRI maintains ownership of all copyrights for any publication, information or data, submitted for publication.

Please contact me (203-798-5701) with any questions relative to this request.

Sincerely,

A handwritten signature in black ink that reads "Gordon Hansen". The signature is written in a cursive style with a large, prominent "G" and "H".

Gordon Hansen
Steering Committee Chair