PQRI

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September 29, 2006

Ms. Helen Winkle, Director
Office of Pharmaceutical Sciences
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Ms. Winkle:

The Product Quality Research Institute (PQRI) is pleased to submit for FDA's consideration the *"Safety Thresholds and Best Practices for Leachables and Extractables in Orally Inhaled and Nasal Drug Products"* recommendation, which represents the culmination of the PQRI Leachables and Extractables Working Group's efforts over nearly a four year period. Group representation included industry, academia and the various components of the Agency and drew on the vast expertise of the working group members, as well as comprehensive literature and database analysis and evaluation, and extensive laboratory work.

During the period of study and discussion, the L/E Working Group developed a work plan outlining the goals and activities proposed, established two sub groups – the toxicologists and the chemists – gathered data, built consensus, submitted findings for an independent peer review and their work has now received the full endorsement of PQRI's Drug Product Technical Committee and Steering Committee. The complete report is attached for your review.

We look forward to FDA's response to this submission and welcome any questions or clarifications which may assist you in your review. Please do not hesitate to contact me (203-798-5701) if I may assist you further in this regard.

Respectfully submitted,

Gordon Hansen

Gordon Hansen
Chair, PQRI Steering Committee

cc: Dan Norwood, Chair, Leachables/Extractables Working Group
Terry Tougas, Chair, Drug Product Technical Committee