



March 19, 2003

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike – HFD-001
Woodmont Office Complex II
Rockville, MD 20852-1448

Dear Dr. Woodcock:

The Product Quality Research Institute (PQRI) is pleased to submit for FDA's consideration the attached recommendations from the Aseptic Processing Working Group. This group was formed to address several aspects of FDA's aseptic process concept paper published last year. Group representation included industry, academia and the various components of the Agency.

In addition to drawing on the vast expertise of the working group members, an industry survey was developed to solicit input for various aspects of aseptic processing. The survey was completed by over 45 domestic and international aseptic manufacturing sites and captured data for over 600 individual media fills. The working group considered the survey data as well as existing standards and publications in reaching their final recommendations.

We are pleased to note that the 41-member working group completed its activities in 110 days. Given the diverse composition of the group and the complexity of the issues addressed, the rapid timeframe in which this recommendation was completed speaks to the importance the group placed on its efforts and the significance of having good science available with which to formulate a draft guidance on aseptic processing. It is our hope that future joint efforts can be completed in a similar timeframe that will encourage the use of PQRI as a forum in which scientific regulatory issues can be debated.

Our understanding is that these recommendations will be incorporated in the draft guidance on aseptic processing in preparation by the Agency. Please feel free to contact us if clarifications on the recommendation are needed in preparation of the guidance.

PQRI looks forward to future collaboration with the Agency on additional topics of mutual interest related to the quality of pharmaceutical products.

Respectfully submitted,

Tobias Massa, Ph.D.
Chair
PQRI Steering Committee

Enclosure

cc: Ms. Helen Winkle
Dr. Ajaz Hussain
Mr. Joseph Famulare
Mr. Richard Friedman
Mr. Glenn Wright