Division of Dockets Management (HFA-305)
Food and Drug Administration, 5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

October 20, 2003

Dear Mr. Freidman and Associates:

Thank you for the opportunity to review and comment on the draft guidance for aseptic processing. We certainly appreciate all of the work your committee has conducted to prepare this document. We would like to submit some comments and recommendations that we feel would improve the Draft "*Guidance for Industry Sterile Drug Products Produced by Aseptic Processing – Good Manufacturing Practice*", [Docket Number 2003D-0382].

Our comments relate to Lines 324-326 of Section X. Laboratory Controls. Part D. Alternate Microbiological Test Methods.

The first sentence in Part D recommends the use of rapid methods for in-process control testing and finished product release testing. The applicability of the use of rapid methods for environmental monitoring testing in pharmaceutical environments, e.g., air, water, and contact surfaces, has been demonstrated by presentations at scientific conferences and publications in peer reviewed scientific journals. A list of the different presentations and scientific publications is listed in the reference section. Therefore, it's our recommendation that environmental monitoring should be added to the sentence to read "Other suitable microbiological test methods (e.g., rapid test methods) can be considered for environmental monitoring, in-process control testing, and finished product release testing".

The second sentence in Part D stated "the use of test methods that, upon evaluation, demonstrate increased accuracy, sensitivity, and reproducibility". The term "increased" means that the methods must be better than the standard test. The statement can be misunderstood as an endorsement to methods that will only provide better results than the standard test. References 11 and 12 describe the different initiatives by the Parenteral Drug Association (PDA) and as published in *Pharmacopeial Forum* (USP) to provide guidance for the validation of alternate microbiological test methods. Both organizations report that when validating alternate methods, e.g., rapid methods, the requirement for acceptability is "equivalent" results to standard methods. By definition in the compendia, "equivalent" means results that are equivalent or better. Therefore, it's our recommendation to replace the word "increased" with the word "equivalent" and to modify the sentence to reflect these changes as "upon validation, demonstrate equivalency to standard methods regarding accuracy, sensitivity, and reproducibility".

I would like to thank you for giving us the opportunity to comment and make recommendations to the document. Thank you very much for your attention and I look forward to hearing from you soon.

Should you require copies of any of the referenced documents, you can contact me at the following e-mail address, luis@genprosys.com.

Sincerely,

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