



Ms Lonnie Warren-Myers
Division of Dockets Management (HFA-305)
5630 Fisher Lane
Room 1061
Rockville, MD 20852
USA

29 September 2004

Dear Ms Warren-Myers,

Aseptic Technologies, a fully owned subsidiary of GlaxoSmithKline Biologicals requests to participate in CBER's "Regulatory Site Visit Training Program" at our Les Isnes facility in Belgium. We will provide a full two-day, hands-on training for up to five CBER reviewers demonstrating the new technology designed into our advanced filling equipment for aseptically filling sterile solutions into a pre-sterilized sealed container/closure system. This filling system is known as "Closed Vial Filling Line" (CVFL System) and presents a filling system based on new technology for aseptically filling sterile solution to ensure a high probability of sterility assurance.

The CVFL technology, equipment design/operation principles and Master Validation Plan have been previously discussed with CBER during the development phase at a pre-BLA meeting held January 15, 2003.

We now have a fully validated filling system which we will use for filling stability lots and clinical supplies. We will use this equipment for the training.

We extend the invitation to host the two-day training session during the following weeks in 2005:

March 14-19
April 4-8
April 11-15
April 18-22

If these times are not agreeable, please send us alternate dates. We look forward to CBER's acceptance of this invitation.

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VDC-fh-300904-L06

2004N-0408



For correspondence concerning this invitation, please contact Doris Conrad at 610-525-6484 or by e-mail: herbconrad@comcast.com.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Christian Vandecasserie".

Christian Vandecasserie, PhD
President, Aseptic Technologies
Parc Scientifique Crealys
Rue Camille Hubert 7-9
5032 Les Isnes, Belgium

cc : John Finkbohner