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September 16, 2011
Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Amendments to Sterility Test Requirements for Biologic Products
Docket No. FDA-2011-N-0080 (Comments due, Sept 19, 2011)

Dear Sir/Madam,

PDA is pleased to support FDA's Amendments to Sterility Test Requirements for Biologic Products. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in drug substance and drug product sterility testing, including members representing our Biotechnology, Regulatory Affairs and Quality, and Science Advisory Boards.

PDA has no suggested revisions on this proposed amendment of the regulations. We support both the timing and content of your proposals which are intended to provide manufacturers of biological products with greater flexibility and encourage the use of state-of-the-art test methods.

For your information, in a letter to FDA dated June 27, 2011, in response to the *Periodic Review of Existing Regulations* (Docket No. FDA-2011-N-0259), PDA has already identified 21 CFR 610.12 as a regulation that is outdated and possibly causing harm. This regulation can cause unnecessary risks to drug product sterility by requiring that manufacturers conduct a bulk sterility test just prior to filling. A copy of that letter is attached, and reference to it will show in detail why and how this regulation should be modified. See:



PDA Comment
FDA-Bulk Sterility Tes

PDA supports FDA's expedited review and implementation period for these amendments to the Sterility Requirements for Biologic Products.

Sincerely,

Richard Johnson
President, PDA

CC: Robert L. Dana, PDA
Rich V. Levy, PhD, PDA
James Lyda, PDA