BIOTECHNOLOGY INDUSTRY ORGANIZATION
1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

September 19, 2011

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

Re: Docket No. FDA-2011-N-0080: Amendments to Sterility Test Requirements for Biological Products

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the "Amendments to Sterility Test Requirements for Biological Products." BIO supports the FDA's proposed amendments to the sterility test requirements for biological products. Appropriate sterility testing is important to ensure safe, pure, and potent biological medicines and we appreciate FDA's efforts to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

GENERAL COMMENTS:

BIO commends the Agency's proposal to amend Sec. 610.12 to promote improvement and innovation in the development of sterility test methods, to address the challenges of novel products that may be introduced to the market in the future, and to potentially enhance sterility testing of currently approved products. Further, we welcome the removal of the specified sterility test requirements for bulk material and the added flexibility proposed for test methods especially in light of BIO's June 27, 2011, comments on the "Periodic Review of Existing Regulations; Retrospective Review under Executive Order 13563" (Docket No. FDA-2011-N-0259) recommending the removal of the requirement for performing the bulk sterility test for recombinant therapeutic proteins and monoclonal antibody products.

In keeping with the Agency's goal to increase the use of rapid and sensitive technologies and reduce the risk and cost to the Sponsor, we ask for clarification regarding validation of novel methods and any methods that deviate from the U.S. Pharmacopeia (USP) compendia.

To validate a USP sterility test, Sponsors need to ensure that the test sample matrix does not interfere with the detection using a bacteriostasis and a fungistasis assay. However, to validate novel test methods for Cellular and Gene Therapy products it appears that the Sponsor not only has to test the matrix effects, but also validate the new method against the USP method as described in the "Draft Guidance for Industry Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products" of February 2008. This would impede the use of innovative technologies, which may provide important benefits in terms of rapidity and sensitivity, and increase the risk and cost to the Sponsor.

We would greatly appreciate clarification on the Agency's intent with regard to validation of new test methods. Specifically, we recommend that the Agency avoid duplicative testing requirements, and allow the manufacturer of the technology or a third party to perform the validation of new methods.

In conjunction with efforts to modify the US requirements for biologic sterility testing, we encourage the Agency to continue harmonization efforts at the International Conference Harmonisation level to standardize acceptability for rapid tests.

CONCLUSION:

BIO appreciates this opportunity to comment on the "Amendments to Sterility Test Requirements for Biological Products." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Managing Director, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)