



November 20, 2014

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

Re: Docket No. FDA-2014-N-1110: Revocation of General Safety Test Regulations That Are Duplicative of Requirements in Biological License Applications

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the proposed rule "Revocation of General Safety Test Regulations That Are Duplicative of Requirements in Biological License Applications."

BIO represents more than 1,000 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.

BIO would like to commend the FDA on retrospectively reviewing its regulations to promote improvement and innovation. In particular we fully support FDA's decision to amend the biologics regulations by removing the general safety test (GST) requirements for biological products. This is a positive step both in eliminating the use of an assay that is no longer needed to ensure the safety of products based on more advanced testing that is now being conducted and also, importantly, reduces the use of animals. We hope that other health authorities around the globe will follow the FDA's lead.

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