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October 29, 2008

Office of the Secretary (Room 502)
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: Section 102 Certificate Requirements

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Consumer Product Safety Commission (CPSC) for the opportunity to submit comments on implementation of the requirements for certificates for conformity testing and third party testing under Section 102 of the *Consumer Product Safety Improvement Act of 2008* (CPSIA, P.L 110-314). BIO shares CPSC's commitment to ensuring that consumer products are of the highest quality and purity. However, unlike most consumer products intended for children, such as toys, jewelry, or cribs, biopharmaceuticals are subject to stringent Food and Drug Administration (FDA) regulations governing manufacturing, quality testing, packaging, and import and are dispensed by licensed healthcare professionals. In order to reduce duplication with existing FDA regulations and minimize any unnecessary reporting burden, we ask CPSC to exempt pharmaceutical products from the Section 102 general conformity certification requirement.

BIO represents more than 1,200 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 and its member companies have worked closely with the FDA to ensure that the United States' drug supply is safe, secure, and reliable, and that Americans can be confident that when they use an FDA-approved prescription drug or biologic, the

medicine will be safe and effective and work as intended. FDA's regulatory standards are among the most rigorous in the world and BIO's members will continue to comply with the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) that ensure the safety of prescription drugs. For example, the FFDCA requires that all new prescription drugs be approved by FDA as safe and effective for their intended use prior to marketing and distribution. In addition, our members' facilities that manufacture prescription drugs and biologics for the U.S. market must comply with FDA's current Good Manufacturing Practice (cGMP) requirements to ensure that the manufacture of their prescription drugs and biologics can be reproduced consistently and in accordance with the agency's quality standards. Our members are responsible for ensuring the safety of both the domestic and foreign-manufactured ingredients used for their prescription drugs and biologics. BIO members that are U.S. manufacturers of finished dosages that use imported ingredients test and validate the safety, purity, and consistency of those ingredients that they use in the manufacture of their products.

While pharmaceutical products packaging is extensively regulated by the FDA, some elements of the product packaging fall under the jurisdiction of the CPSC. The Poison Prevention Packaging Act (16 C.F.R. 1700.14) requires that certain orally administered human drugs and controlled substances be packaged in child-resistant containers. This regulation is undoubtedly in the best interest of the public health. The *Consumer Product Safety Improvement Act of 2008* adds new requirements. It states that "every manufacturer of a product which is subject to a consumer product safety rule under this Act or similar rule, ban, standard, or regulation…shall certify, based on a test of each product or upon reasonable testing program, that the product complies with all rules, bans, standards, or regulations applicable to the product under this Act or any other Act enforced by the Commission". The language could be interpreted to require that orally administered pharmaceutical products intended for children must be accompanied by a certification upon entering the country. BIO is concerned that this would create a significant reporting burden without a significant health benefit, and believes that it would be appropriate to exempt pharmaceutical products from the general conformity certification requirement.

Should the above requested exemption not be granted, we ask that CPSC clarify that any bulk drug product (i.e., unpackaged final product) provided by the manufacturer to a pharmacist that is packaged and distributed by the pharmacist in child-resistant packaging be exempt. For example, many small and large sized pharmaceutical containers are shipped to the pharmacist, who then dispenses the drug to the patient in child-resistant bottles or packaging. The following pharmaceuticals containers should be exempted from the import certification process because the child safety aspects of packaging are already fully addressed for these products and the certification would add additional burden without providing additional protection of public health.

- Small containers filled by the pharmaceutical manufacturer;
- Small-count pharmaceutical product containers;
- Large-count pharmaceutical product containers.

CONCLUSION:

BIO appreciates this opportunity to comment on the requirements for certificates for conformity testing and third party testing under Section 102 of the *Consumer Product Safety Improvement Act of 2008.* We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization