October 3, 2016

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

Re: Docket No. FDA–2016–D–2268: Insanitary Conditions at Compounding Facilities; Draft Guidance for Industry; Availability

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the Draft Guidance entitled "Insanitary Conditions at Compounding Facilities" (Draft Guidance).

BIO is the world's largest trade association representing 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.

GENERAL COMMENTS:

BIO applauds the issuance by the FDA of this Draft Guidance as it recognizes the importance of sanitary conditions within compounding facilities. BIO also recognizes the inherent challenges that the FDA faces in regulating a safe and sterile environment for compounding as most compounding pharmacies do not register as 503B outsourcing facilities. Thus, we are pleased to see that the FDA encourages state regulators to pay close attention to the cleanliness of compounding pharmacy operations and to take action where necessary.

Similarly, BIO believes that the current Draft Guidance could go even further to convey the importance of this issue with state regulatory agencies. Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

A February 2016 report[1] from the Pew Charitable Trusts entitled, "National Assessment of State Oversight of Sterile Drug Compounding," highlighted significant state deficiencies regarding oversight of sanitary compounding conditions:

- To effectively oversee compounding activity, state regulators need reliable information about facilities that compound and their ability to meaningfully respond

[1] Pew Charitable Trusts, "Best Practices for State Oversight of Drug Compounding" (February 2016).

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to any safety deficiencies. However, only 24 of 43 states (56 percent) responding to the Pew survey reported tracking the number of pharmacies performing sterile compounding in their state. Slightly fewer (19 of 43) said their state tracked the number of out-of-state pharmacies shipping or dispensing compounded drugs into the state.

- Only about half of states responding (21 of 43) reported that they required sterile compounding to fully conform to the widely recognized quality standards set by the U.S. Pharmacopeial Convention (USP) in its General Chapter Pharmaceutical Compounding—Sterile Preparations. [2]

- Twenty-eight states (65 percent) said they allowed pharmacies to compound without patient-specific prescriptions even though state policies permitting compounding without a prescription for human use conflict with Federal law.

- Sixty percent of states responding (26 of 43) do not require compounding pharmacies to report (to either the state or the FDA's MedWatch) serious adverse events and reactions related to sterile compounding.

Given the lackluster oversight by most states to oversee certain safety aspects designed to ensure sanitary compounding, BIO recommends that FDA take the steps necessary to enforce the safety standards codified under section 501(a)(2)(A) of the FD&C Act. Accordingly, FDA should strongly recommend that state authorities report serious adverse events to the FDA's MedWatch reporting system. BIO also recommends that FDA strongly encourage states to act in accordance with Federal guidelines pertaining to compounding without a prescription (*e.g.,* anticipatory fills).

CONCLUSION:

BIO appreciates this opportunity to comment on the Draft Guidance "Insanitary Conditions at Compounding Facilities". We recognize that access to medically-needed compounded medicines is highly important; but access cannot and should not come at the expense of product quality and patient safety. As such, we applaud FDA for recognizing the importance of sanitary conditions within compounding facilities. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Cartier Esham, Ph.D.
Executive Vice President, Emerging Companies Section &
Vice President, Science & Regulatory Affairs
Biotechnology Innovation Organization

[2] BIO believes that adherence to all applicable USP guidelines regarding compounding is an important component in ensuring patient safety. See BIO's comments to FDA's Draft Guidance "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act" submitted July 18, 2016.