Biotechnology Industry Organization

September 13th, 2013

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

Re: Docket No. FDA–2013-D-0710: Draft Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the "Draft Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection."

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 and its members believe that the quality and integrity of their products are among the most important responsibilities they have to the patients and public that they serve. As FDA acknowledges in the Draft Guidance, there are many situations which cause delays in an inspection, many of which are outside the control of the facility. While BIO member companies strive to incorporate a strong culture of quality and adhere to all FDA rules and regulations, we are concerned that under the Draft Guidance an inspector would have the authority to characterize a delay or a limitation as sufficient to adulterate a drug without providing the Sponsor sufficient notice or due process. BIO believes that prior notice, written or otherwise, should be given to the owner operators prior to concluding that a particular delay or limitation is one that adulterates drugs, as well as notice of which drugs would be rendered adulterated. In all cases, owner operators should be allowed the opportunity to provide a reasonable explanation for the delay or limitation and work with FDA on curing the alleged deficiency. FDA should recognize all good-faith efforts by a facility to comply and permit an owner operator to provide a reasonable explanation for any delay, denial, or limitation and allow the FDA and owner operator to come to a mutually acceptable solution in order to advance the common goal of establishing and securing an inspection regime that advances patient safety.

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LINE ITEM EDITS:

1. *Environmental Health and Safety or Other Limitations*

There may be certain circumstances when entry into certain areas of a facility is appropriately restricted. This should not be perceived as refusing entry to an inspector. To provide clarity regarding specific situations when access limitations are warranted, we ask FDA to add the following after the text in lines 161 and 219:

> Limitations on room entry based on Environmental Health and Safety issues or other reasons, such as gowning qualification for entry into the aseptic core, must be considered.

2. *Limiting Photography*

Many companies have restrictions on photographs on site as a matter of company policy in order to protect intellectual property. Companies and FDA occasionally negotiate to allow photographs of a certain area, but only after a discussion between the company and FDA. The Draft Guidance appears to state that any limitation on photographs will render the drugs adulterated. Further, FDA must take into consideration privacy legislation in countries outside the US that may prevent or limit photographs that include staff members. In order to balance protection of intellectual property and FDA's need to take photographs, we ask FDA to edit the text as follows:

> "Photographs ~~are an~~ may be an integral part of an FDA inspection because they may present an accurate picture of deficient facility conditions. Not allowing legally permissible photography by an FDA investigator may be considered a limitation if such photographs are determined by the investigator(s) to be necessary to effectively document a deficient facility condition and upon prior discussions between the investigator(s) and owner, operator, or agent to ensure protection of owner operator intellectual property ~~conduct that particular inspection~~. Examples of deficient conditions or practices effectively documented by photographs may include, but are not limited to: evidence of rodents or insect infestation; faulty construction or maintenance of equipment or facilities; product storage conditions; product labels and labeling; and visible contamination of raw materials or finished products."

CONCLUSION:

BIO appreciates this opportunity to comment on the "Draft Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

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