



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-N-0365: Administrative Detention of Drugs Intended for Human or Animal Use

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 "Administrative Detention of Drugs Intended for Human or Animal Use."

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 appreciates the timely release and comprehensive nature of this proposed rule to implement Title VII of the Food and Drug Administration Safety and Innovation Act (FDASIA). We also appreciate the Agency's effort to ensure regulatory ease and efficiency, as the proposed rule closely follows the administrative detention paradigm already in place for other FDA regulated products.

Broad Definition of "Adulterated/Misbranded"

BIO agrees that the policy purpose of administrative detention is to protect the public by preventing distribution or use of drugs that may be adulterated or misbranded. Because the term "adulteration" is so broad, BIO wants to make certain there are appropriate parameters in place to ensure that patients continue to have access to safe medications. While we note the proposed rule does attempt to ensure that administrative detention is used only as necessary and appropriate by requiring prior approval by the FDA District Director, we also suggest that the detention standard include an element of potential risk of public harm. Adding this element to the standard would ensure that the rule as implemented fully reflects the intended policy purpose of protecting public health, which also includes ensuring patient access to medicines.



We note that this proposed rule also has a multivariate interaction with the "FDA Draft Guidance for Industry – Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection". This Draft Guidance provides the inspector, with district director approval, the ability to determine that a firm is impeding an inspection, the outcome of which is the drug product can be labeled adulterated/misbranded, and thus withheld from patients without due process. Without due process or acknowledgement of risk/benefit considerations for patients, unnecessary drug shortages may occur. Clarity in both the Draft Guidance and the Administrative Detention proposed rule is essential to limit variability in interpretation by the district investigators.

SPECIFIC COMMENTS:

1. *(g) Appeal of a detention order*

As written, the proposed rule allows for appeals by "a person who would be entitled to claim the drugs, if seized." BIO is concerned that if a distributor has title to the product that is seized, manufacturers would not have the ability to appeal. BIO asks the FDA to clarify that it is not the intent of the proposed rule to limit a manufacturer's ability to appeal a detention order.

2. *Part I-General Enforcement Regulations, Subpart L—Administrative Detention of Drugs Intended for Human or Animal Use, Administrative detention of drugs (h)(2)*

BIO appreciates that movement may be approved in order to prevent interference with an establishment's operations or harm to the drugs. Due to the unique nature of biologics and required environmental controls such as cold-storage, BIO wants to ensure there is appropriate flexibility for movement of detained drugs outside of the establishment/facility (e.g., to an approved storage facility) in order to preserve product integrity while in the detention process. As such, we ask FDA to revise section (h)(2) as follows:

If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work [or to an approved storage facility pending the work](#) needed to put them in final form.

CONCLUSION:

BIO appreciates this opportunity to comment on the proposed rule "Administrative Detention of Drugs Intended for Human or Animal Use." 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)