Biotechnology Industry Organization

September 23rd, 2013

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

Re: Docket No. FDA–2013-D-0836: Draft Guidance for Industry on Pre-Launch Activities Importation Requests

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Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the "Draft Guidance for Industry on Pre-Launch Activities Importation Requests."

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.

Historically, FDA relied upon a simple and informal system to allow a Sponsor to import drug products pending marketing approval in order to ensure patient availability of product immediately upon approval. A Sponsor requested the import approval and referenced the pending application, FDA granted approval to import, and the Sponsor was free to distribute product when the pending application was approved. BIO appreciates the Agency's efforts to create a more formal and predictable pre-launch activities importation request (PLAIR) process, but is concerned that the program, as outlined in the draft guidance may have the unintended consequence of delaying the availability of product to patients following a Sponsor's receipt of an approved drug application. BIO questions and asks FDA to clarify the problem that FDA seeks to solve by instituting a more formal PLAIR process. To the best of our knowledge, the prior system did not result in premature distribution of product, and product always remained subject to the rules and regulations of the Federal Food, Drug, and Cosmetic Act (FFDCA), including the prohibition against the introduction or delivery for introduction into interstate commerce of any misbranded drug under section 502 or any article not subject to new drug approval under section 505.

Under the proposed PLAIR process, by submitting a PLAIR, a Sponsor is by default accepting that FDA has refused entry of the product, that the product must be "reconditioned" per the terms of the PLAIR, and that the Sponsor has opted not to request a hearing on refusal of admission. These elements of the proposed PLAIR program create a high bar, and the appearance that FDA is trying to discourage pre-

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launch importation activities. BIO is concerned that program participation requires Sponsors to forego legally enforceable due process rights related to the detention process. In addition, the program has the potential to delay patient access by requiring a Sponsor to follow-up with FDA to verify that the terms of the PLAIR have been met and that the product conforms to the application prior to release and despite being subject to the FFDCA including 502 and 505, BIO requests FDA clarify the type of terms FDA may demand under the proposed program how it will determine that the product imported under a PLAIR "conforms to the application."

In addition, we note that the draft guidance recommends that Sponsors submit a PLAIR not more than 60 days before the user fee goal date. This seems to be a short time period for FDA to act upon the request and respond. If indeed 60 days is not enough time for FDA to grant a PLAIR, a Sponsor would have little time to actually get the product shipped and imported so that it can be on hand and ready for launch; this effectively defeats the purpose of the PLAIR.

CONCLUSION:

BIO appreciates this opportunity to comment on the "Draft Guidance for Industry on Pre-Launch Activities Importation Requests." 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)