Biotechnology Industry Organization

November 5th, 2013

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

Re: Docket No. FDA-2013-D-0984: Draft Guidance for Industry on Specification of the Unique Facility Identifier System for Drug Establishment Registration

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Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the "Draft Guidance for Industry on Specification of the Unique Facility Identifier System for Drug Establishment Registration."

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.

BIO thanks FDA for releasing this Draft Guidance specifying the Data Universal Numbering System (DUNS) number as FDA's preferred Unique Facility Identifier (UFI) system in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA) sections 701 and 702. BIO supports FDA's effort to have a single facility identification system in order to facilitate FDA's activities that follow-on to registration which help secure patient and consumer safety, and we have several recommendations and requests for clarification on the proposal put forth in the Draft Guidance.

First, there are currently a number of facility identification numbers used for site identification, registration, and supply chain tracking purposes, of which the DUNS number is one. BIO is concerned that although the use of the DUNS number allows for a number available in the public domain, the process for obtaining a DUNS number does not provide the necessary control to ensure the address registered for a site is accurate to prevent duplication of numbers for the same site or same site address. For example, the process for obtaining or updating an address associated with a DUNS number requires two independent documents to verify the address. These documents may be obtained over the internet without input or notification to the concerned company that owns the site. Therefore, the process does not ensure there is a single, unique number active for a specific site and that no duplication occurs because the site address may have been entered inconsistently.

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As such, BIO suggests FDA consider making the Global Location Number (GLN), obtained from GS1, the preferred UFI system for the following reasons.

1. The GLN contains embedded Global Positioning Satellite (GPS) coordinates to identify the unique geographic location of the manufacturing facility.

2. The GLN provides for a unique number, available in the public domain, for a nominal cost to the manufacturer or Sponsor. GS1, the issuing standards body, will maintain control of the GLN *vs*. the address/GPS, providing control of the facility registration numbering process and preventing duplication. Once the GLN number is assigned, the manufacturer or Sponsor assumes control of the GLN directly.

3. The GLN, as an internationally recognized GS1 standard, also provides a means for global harmonization and eliminates the uncertainty of obsolete legacy identifiers.

As a result, the GLN contains added security for manufacturers and mitigates many of the concerns discussed above. BIO believes that while there is a nominal fee associated with the GS1 service, the added security provided by GLN use negates any concerns regarding the charge of a nominal fee.

Second, FDA currently requires a facility identification number for any foreign site manufacturing for clinical trials. BIO requests clarification on whether this Draft Guidance is only intended for commercial sites, or whether it also applies to U.S. sites manufacturing for clinical trials.

Finally, as the Draft Guidance does not describe all necessary requirements for drug establishment registrations, BIO recommends that this Draft Guidance be combined with the current "Guidance for Industry, Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing Draft", to provide a Sponsor with a single document containing the necessary requirements on this particular topic.

CONCLUSION:

BIO appreciates this opportunity to comment on the "Draft Guidance for Industry on Specification of the Unique Facility Identifier System for Drug Establishment Registration." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

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