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November 18, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-N-0334: Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements

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 "*Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements*." BIO agrees that electronic safety reporting would enhance patient safety and support FDA's public health mission by allowing the agency to more rapidly review postmarketing safety reports and identify emerging safety issues. In fact, 80% of adverse event reports submitted by biopharmaceutical companies to the Center for Drug Evaluation and Research (CDER) are already filed electronically.ⁱ BIO is pleased to offer the following comments to ensure that all companies – large and small – are able to successfully submit adverse event reports electronically.

BIO represents more than 1,200 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.

I. Web-based Portal

BIO believes that in addition to the Electronic Submission Gateway (ESG), a web-based interface for the submission of safety reports is critical for companies to comply with the electronic submission requirement. The portal will be of greatest benefit if:

- No charge is associated with usage to eliminate barriers for small companies.
- The portal provides a receipt/acknowledgement indicating if the submission was successfully received or if the delivery failed. This will enable companies to take appropriate follow-up action.
- The portal accepts ICH compliant XML files, which may be generated and submitted to the portal and/or the ESG.
- Companies may utilize both the portal and ESG rather than being forced to select one system.

In addition, clarification of the following items would be helpful in preparation for the migration to mandatory electronic submissions of safety reports:

- The term “web-based electronic submissions portal” does not always seem to be utilized consistently in the proposed rule. What does FDA envision when the term “portal” or “web-based form” is used? It is not entirely clear in the notice if this refers to the MedWatch^{Plus} initiative or something different.
- Will training or “qualification” be required prior to submissions via the portal?
- Can a sponsor utilize follow-up links to the original report when submitting via the portal?

II. Temporary Waiver

In the event that a company cannot electronically access the ESG or portal, the mechanism for requesting temporary waivers should include non-electronic means, such as requesting a waiver via phone or fax.

III. Biological Product Deviation Report (BPDR)

BIO believes that the proposal to require electronic submission of Biological Product Deviation Report (BPDR) is reasonable. However, to ensure a complete description of the event is provided, please consider modifying the current web-based form to allow more than 2000 characters to be included in the *event description field*.

IV. Effective Date

The effective date of the final rule should be dependent not only upon the final rule publish date but also upon the availability of the web-based portal for submission of safety reports.

Conclusion:

BIO appreciates this opportunity to comment on proposed rule on “*Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements.*” We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

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

ⁱ The Pink Sheet, *Adverse Event Rule Would Require e-Conversion Of 20 Percent Of Submissions*, August 24, 2009.