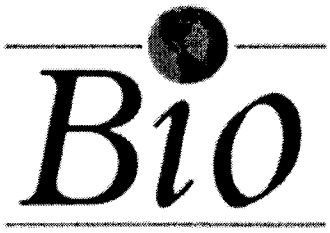

Biotechnology Industry Organization
1225 Eye Street NW, Suite 400
Washington, DC 20005

April 5, 2004

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

Re: Docket No. 2004D-0041, Federal Register: February 5, 2004 (Volume 69, Number 24, pp. 5552-5553)

Dear Sir/Madam:

The following comments are provided by the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in 45 U.S. states and 32 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial, and environmental biotechnology products. BIO appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) Draft Guidance for Industry, Providing Regulatory Submissions in Electronic Format – Content of Labeling (Docket 2004D-0041).

General Comments

BIO recognizes the importance of both of the goals this draft guidance seeks to achieve – allowing FDA to receive information related to a drug or biological product application electronically and in a format conducive to the most efficient and effective processing and archiving and allowing for the use of such information in new systems designed to reduce and prevent medical errors. We also acknowledge the agency's participation with other entities to identify a format that can be used when product labeling may be needed for e-prescribing, in a computerized patient record, or in an exchange of patient information.

We are concerned about the impact and the timing of full implementation of a transition from PDF to SPL format for labeling and we have a number of questions we hope the agency will address prior to publishing a final guidance on this issue.

The draft guidance indicates that at the end of a transition period, FDA would only accept labeling submissions in SPL format. BIO requests that any final document specifically address how labeling already under review at that point would be handled, as well as how the agency would deal with amendments to such pending labeling.

BIO is concerned as well about the proposed timeframe for complete transition and whether that timeframe is adequate. The Draft guidance suggests the agency plans to publish the final document in June and hopes to complete the transition by the end of 2004. We urge the agency to provide a transition period that will appropriately ensure both that applicants are able technically to submit labeling in SPL format and the agency can process and archive it as anticipated. The SPL concept is new to most BIO member companies and time will be needed for development, testing and validation, and availability of software to allow conversion from PDF to SPL. We believe it may be extremely difficult for many in the industry to be ready by the end of 2004, in light of multiple actions that must be taken first. BIO requests the opportunity to work with the agency to gain the information necessary for both the agency and the industry to know what an adequate transition period is.

Our questions, listed below, are designed to elicit sufficient information to understand fully what may be expected and what may occur as a transition takes place and post-transition.

(1) Potential exceptions. -- Although the agency notes, as usual, that Guidance is not binding, there appears to be no viable option for sponsors submitting labeling in anything other than the new SPL format. We base this impression on the statements at lines 97-104 that the agency is developing an automated system using SPL, plans to identify SPL as a format that can be used, and will not be able to use PDF format once the transition is complete. Is this an accurate reading of the agency's intention, or will there be the possibility of exceptions to the SPL submission expectations? Further to this point, will 21CFR Part 11 apply in its entirety to SPL labeling submissions, or may there be exemptions?

(2) Resubmission. – Once the agency has made the transition from PDF to SPL, will labeling changes need to be submitted in SPL format? To what extent will this require that the original labeling, or any earlier amended labeling, be re-formatted in SPL and then re-submitted?

(3) Integration with the Electronic Common Technical Document. – Is the SPL standard integrated with the e-CTD requirements? Has any analysis been done in the marketplace for vendor products that support the SPL standard? Is HL7 working with vendors to develop solutions for SPL? Have any pilot

studies been done by FDA to ensure that the agency is technically able to accept SPL format? What is the nature of any such pilots? Will lifecycle management be implemented similar to the e-CTD?

BIO recommends strongly that FDA address the SPL concept in conjunction with the evolving ICH e-CTD standards and those FDA efforts be coordinated with the EMEA to avoid the emergence of varying standards in ICH regions. Such an outcome would not be in keeping with efforts toward international harmonization.

(4) Technical evaluation of SPL. – The draft Guidance indicates that FDA has adapted Clinical document Architecture (CDA) for labeling. Specifically how was the CDA adapted? Was the SPL standard evaluated by comparison with other standards, or is such side-by-side comparison ongoing or planned?

In conclusion, BIO agrees with the need to ensure that product labeling can be used most effectively in medical and other settings where patient safety is paramount. We recognize that as technology evolves in prescribing, information exchange, and record-keeping, essential drug and biological product-related information must adapt as well. BIO, like FDA, wants to ensure that the formatting of such information will indeed work as expected and integrate with other systems as necessary. We are committed to work with the agency toward optimal achievement of this goal. Thank you for providing us with the opportunity to begin the dialogue by commenting on this Draft Guidance. We look forward to additional opportunities to discuss the questions outlined above.

Sincerely,

Sara Radcliffe

Sara Radcliffe
Director
Science Policy and Bioethics