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January 22, 2001

Dockets Management Branch
HFA-305, Room 1061
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: DOCID:fr29de00-87

To Whom It May Concern:

These comments are submitted in response to the Food and Drug Administration's Federal Register Notice, dated 29 December 2000 (65 FR 251 at 83069) on the use of the extensible Markup Language (XML) to create a cumulative table of contents for investigational New Drug (IND) applications. MojoCommerce LLC provides enterprise-scale data and information management solutions specifically designed for FDA-regulated businesses. We firmly believe in the promise of XML as a breakthrough information management technology and welcome the opportunity to assist with the Agency's movement towards XML as an electronic data communication standard.

Our intent for these comments is to inform the public, the Agency and industry that XML is a technology that can be used today to easily and cost-effectively present regulatory submissions to the Agency. Further, we seek to advise the public, the Agency and industry of the current availability of our enterprise-scale software platform for XML-based information management, which will easily permit the development of the FDA's proposed DTD (or any DTD which follows the XML standard), along with the ability to manage large volumes of data against this DTD structure in a secure platform which was designed in consideration of 21 CFR Part 11. Hopefully, knowledge of the availability of such a platform (and the certainty that more solutions will be available from other vendors in the future) will encourage the Agency and industry that XML can be used cost-effectively to improve information management between the Agency and industry.

In the Federal Register notice, the Agency asked a number of questions which we would like to respond to individually. It is important to note that we are answering these questions as a vendor of XML software, and our responses will naturally reflect our approach to using XML. We would ask the readers of these comments to think of our responses in terms of what is possible now with XML, independent of a specific vendor's implementation of a tool or platform.

- How difficult is it for you to create and maintain the XML files needed for the cumulative table of contents?

  Manual coding of XML can be a tedious process. MojoCommerce's XML information management platform, Matrixml™ permits someone with absolutely no knowledge of XML structure or coding to develop Document Type Definitions (DTDs) of infinite complexity, along with style sheets and the corresponding database representations, using only a browser. As a result, the IND cumulative table of contents structure can be created in less than an hour using a browser, form-based interface. Immediately thereafter, multiple documents can then be immediately created against this structure and published for

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viewing with an Internet browser. It is these documents created from the DTD "template" that would be submitted to the Agency as regulatory filings.

- How difficult will it be for you to incorporate the preparation of an XML document in your submission preparation process?

MojoCommerce has designed its product, Matrix*ml*™, to be implemented using only an Internet Web browser, specifically to permit individual organizations to be able to begin using the platform almost immediately. Without this type of platform, manual generation, management, change control and publication of flat-file XML documents would need to be handled by multiple software tools, increasing complexity and cost to individual companies. We anticipate many companies will choose to begin working with XML in this way, and this may unfortunately impede the acceptance of XML as a data and information management technology for regulatory filings. We believe FDA-regulated companies could cost-effectively begin developing XML-based regulatory filings within days, using Matrix*ml*™.

- Do you have suggestions for improvements on the cumulative table of contents?

The Module TOC uses element attributes to store hypertext links to other documents and datasets. Our product, Matrix*ml*™, certainly can provide links to external files, but it can also store files within a relational database as part of the XML document structure. Essentially the data becomes an integral part of the table of contents without the need for cross-reference codes. Used as an XML management platform, Matrix*ml*™ would eliminate the need for explicitly defining the path and filename. Also, the data is more secure since it resides internally to the document rather than under the control of an external file system.

We believe it is important for the Agency to follow the open-standard nature of XML to ensure industry maintains multiple options for exchanging information with the Agency. It is also important for the Agency to be able to securely manage XML documents and data received from industry. The cumulative TOC and other XML-based submission documents should be designed to meet both goals.

- Are you interested in piloting the cumulative table of contents in electronic INDs with the agency?

MojoCommerce would welcome the opportunity to work with the US Food and Drug Administration and /or an industry representative on piloting a cumulative table of contents for electronic INDs. In particular, due to Matrix*ml*™'s import functionality, native change control, versioning and workflow routing capability, we believe the Agency could very effectively use Matrix*ml*™ to accept, manage, edit, route, and publish XML-based electronic IND filings in an integrated, cost-effective platform with unparalleled security features.

- Are you interested in working with us to develop tools to be used with the cumulative table of contents?
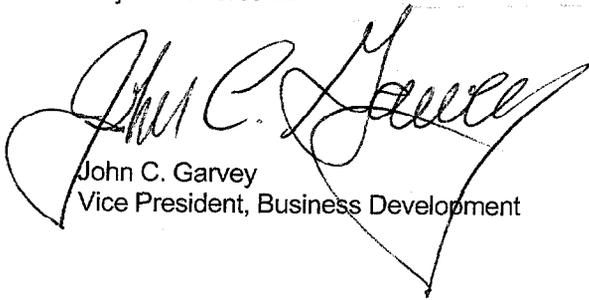
See paragraph above.

- Do you have other comments or suggestions?

  We would welcome the opportunity to meet with the Agency demonstrate the capabilities of our product and to establish a working relationship to further development towards an XML IND standard.

Sincerely,
MojoCommerce LLC

John C. Garvey
Vice President, Business Development