

**Aventis Pharmaceuticals**



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March 29, 2004

Via Fax and UPS

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

Re: Docket No. 2004D-0041

*Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format-  
Content of Labeling; Availability; 69 FR 5552 (February 5, 2004)*

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to provide the following comments on the above-referenced Draft Guidance for Industry entitled, "Providing Regulatory Submissions in Electronic Format-Content of Labeling".

This draft guidance is one in a series of guidance documents on providing regulatory submissions to the FDA in electronic format. In the Federal Register of December 11, 2003 (68 FR 69009), FDA published a final regulation (the electronic labeling rule) requiring that the content of labeling for marketing applications be submitted in electronic format in a form that FDA can process, review, and archive. This draft guidance provides information on how to submit the content of labeling in electronic format for review with new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs).

**Section II. B. New Technology for Processing Labeling and Labeling Changes**

The Guidance describes adoption of a new technology for exchanging information across computer systems called Clinical Document Architecture (CDA). This technology is being developed currently for labeling in a proposed Health Level 7 Standard, Structured Product Labeling (SPL), using XML mark-up language.

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As stated in the draft Guidance, the SPL is currently under development and testing to assure that the standard can be applied to all United States physician and patient labeling, and that the technology will work across all computer systems. The Guidance further specifies that the goal is to complete the agency's transition to SPL format for content of labeling submission by the end of 2004, at which time PDF would no longer be a format that could be used to process, review and archive the content of labeling.

Implementation by the end of 2004 provides only a very limited time to complete development and testing of the proposed SPL. It places an additional burden on the sponsors to participate in the final development and validation of SPL, and, if testing is successful, proceed to develop the internal expertise in XML mark-up language; evaluate and obtain the appropriate computer software; complete internal procedures and user training; and be assured that SPL will work seamlessly with the different electronic publishing systems used by sponsors.

The guidance notes that respondents will spend approximately 44,823 hours submitting the content of labeling to FDA the 1st year for annual reports. The impact on both budget and resources may make this unattainable.

Consideration should be given to either delay implementation of labeling submissions using this method until the SPL testing using XML mark-up language has been completed and validated, or start with a pilot program between the agency and PhRMA companies to assure that the proposed technology will meet both the agency and sponsors' labeling submission requirements and provide a secure method of labeling submissions.

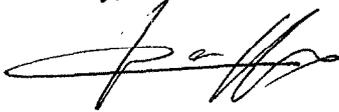
**Section III B. Creating the Content of Labeling File**  
**Section IV. Organizing the Main Submission Folder**

The Guidance proposes that, for submission of labeling changes, only labeling sections or data elements that have changed should be submitted. These labeling sections or data elements should be placed in a single folder titled "SPL".

More direction must be provided as to the requirements for labeling submissions using SPL and created in XML mark-up language. Consideration should also be given to providing an additional guidance or updating the January, 1999 Guidance, Regulatory Submissions in Electronic Format, New Drug Applications, to provide direction as to the information and structure of labeling submissions, and descriptions and naming conventions for the individual data elements.

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on the Draft Guidance for Industry entitled, “ *Providing Regulatory Submissions in Electronic Format-Content of Labeling*” and thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Caffè', written in a cursive style.

Steve Caffè, MD  
Vice President, Head GRAMS – North America  
Global Regulatory Approvals and Marketing Support