



March 23, 2004

Division of Drug Information (HFD-240)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

**RE: Docket 2004D-0041: Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Content of Labeling**

Merck & Co., Inc, is a leading worldwide, human health product company. Merck Research Laboratories (MRL), Merck's research division, is one of the leading U.S. biomedical research organizations. Merck has participated with health authorities from around the globe in the harmonization of regulatory standards.

In the course of bringing our product candidates to market through developmental testing, clinical trials, regulatory review, and approval, we have substantial experience with the benefits in efficiency and economy of electronic submission capability. Accordingly, we would like to take the opportunity to provide comments on FDA's draft guidance for industry entitled "*Providing Regulatory Submissions in Electronic Format—Content of Labeling.*"

According to the Federal Register<sup>1</sup> notice announcing the availability of this draft guidance, FDA proposes to change the way it "processes, reviews, and archives the content of labeling" to support the expanded role for electronic labeling information foreseen by mandates in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as well as in recommendations from the Institute of Medicine and the National Committee on Vital and Health Statistics. These new uses include electronic prescribing and electronic health records. Because existing procedures using PDF cannot support such initiatives, FDA is proposing to adopt a new technology for exchanging information between computer systems that allows information to be exchanged in extensible markup language (XML). The automated system FDA is developing uses Structured Product Labeling (SPL), a standard proposed by Health Level Seven (HL7), a standards development organization accredited by the American National Standards Institute.

## General Comment

Merck agrees with the general concept and direction FDA is taking as outlined in the draft guidance.

## Specific Comments

1. We recommend that an SPL Style Sheet should be in place and available before the recommendations in the final guidance are adopted.
2. We recommend your consideration of alignment of the SPL with the EU “Product Information Management” (PIM) initiative.
3. We request clarification with respect to the use of PDF file format because of two apparently conflicting statements within the draft. Lines 101 – 103 state, “*After the automated system is implemented, PDF would not longer be a format that we can use to process, review, and archive the content of labeling*”. On line 115, however, it says, “*The content of labeling can be provided in PDF or SPL file format.*” We recommend that the statement on line 115 be revised to echo the fact that after implementation of the automated system, PDF will no longer be accepted.

We appreciate FDA’s efforts to improve opportunities for electronic exchange of regulatory information and the opportunity to comment on this draft guidance.

Sincerely,



for Donald Black, MD  
Global Regulatory Policy