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25 March 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Docket No. 2004D-0041: Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format--Content of Labeling; Availability

Dear Sir or Madam:

Amersham Health, Inc. has reviewed the referenced draft guidance for industry and is grateful for the opportunity to provide our comments. Our comments to Docket No. 2004D-0041 are provided on the following page.

These comments are being provided in duplicate as directed in the Federal Register Notice.

If you have any questions, please contact me at (609) 514-6556 or via e-mail at hilary.hafeken@amersham.com.

Sincerely,

Amersham Health, Inc.

Hilary B. Hafeken
Site Publishing Manager
Regulatory Document Management

2004D-0041

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Comments to Docket No. 2004D-0041

Specific Comments:

1. Section II; Lines 102-104: Some pharmaceutical companies currently do not have the tools to author XML documents. Although XML authoring tools are readily available, some sponsors might prefer more sophisticated tools that would complement the publishing software and other systems they plan to implement or already have in place. In addition, some companies will have an issue with the limited time available to either recruit or to train existing staff to obtain the required skills in the use of XML to support these electronic submission requirements.

In summary, the time frame FDA is proposing for transitioning to SPL would not give sponsors adequate time to develop the capabilities or skills to comply with these new requirements.