

April 5, 2004

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

RE: Docket No. 2004D-0041 [Federal Register – February 5, 2004]  
Response to Draft Guidance for Industry on Providing  
Regulatory Submissions In Electronic Format – Content of Labeling

Dear Sir or Madam:

Reference is made to the Federal Register Notice of February 5, 2004, announcing the availability of the Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Content of Labeling.

AstraZeneca has reviewed this Draft Guidance document and we support the concept of providing the content of labeling for marketing applications in an electronic format in which the FDA can process, review and archive. Our comments are in regard to the feasibility of implementing the Structured Product Labeling (SPL) standard and having to do this in what seems to be an unrealistic timeframe.

- We need clarity around the SPL specifications.
- There currently is no vendor support to support this initiative.
- The requirements and capability for converting legacy labeling documents to XML-based documents in the SPL format are unclear.
- We estimate that in a best case scenario it could take approximately six to nine months to set up, configure, validate and test a system once it becomes available.
- Labeling SPL is now competing with other FDA initiatives such as eCTD and well-planned coordination of these efforts within the Agency is essential. Defining an efficient business process is equally as important as implementing a new tool. Sponsors need time to assess the impact this process will have on their authoring and submission processes; authors and publishers; support organizations; and trainers, etc. These types of business preparations are critical to successful implementation of new technologies.
- Sponsors would need to be able to assess this change in their current CTD/eNDA and eCTD processes. For example, if Sponsors were submitting a paper submission, how would they go about providing the SPL? If it was a CTD in eNDA format, would they file the SPL in the same labeling folder as defined in the 1999 Electronic Submissions Guidance, or would it require some additional identification. If it was submitted as

part of an eCTD, are the requirements for this file already spelled out in the eCTD specification document?

We appreciate the opportunity to provide comments for consideration during the development of this Guidance Document. Please do not hesitate to contact us, should you have any questions.

Sincerely,



Sherry Rowell, Associate Director  
Regulatory Labeling  
US Regulatory Affairs  
Telephone: 302-886-8977



Donna M. Whiting, Associate Director  
Regulatory Systems Management  
US Regulatory Affairs  
Telephone: 302-886-2133