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May 26, 2006

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

RE: **Docket No. 2006N-0104, Comment Request on the Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format.**

Dear Madam/Sir:

Hospira, Inc. (Hospira) hereby submits comments to Docket No. 2006N-0104, Comment Request on the Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format. Hospira is responding to two out of the four topics provided for comment. Please find below the topics, followed by the Hospira comments.

Topic # 2

The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

*FDA has underestimated the time required (15 minutes) for sponsor organizations to compile the submission of content of labeling in electronic format. When dealing with .pdf documents, there is a considerable amount of time required to build the bookmarking and hyperlinking necessary for an eSubmission. SPL conversion and validation requires a great amount of time (up to 3 days) to complete the header information and validate the coding necessary for FDA to post the labeling file on the DailyMed website.*

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Topic # 4

Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

- *It would be beneficial, if the FDA was consistent with submission requirements across all of the Reviewing Divisions. Currently, there are instances in which the Office of New Drugs (OND) has conflicting requirements for eSubmissions with the Office of Generic Drugs (OGD). For example, OGD requires MSWord and .pdf documents, while OND does not. As such, extra time and manpower are needed by the sponsor to interpret the division-specific preferences/directives and compile a submission for each of the different Reviewing Divisions within FDA. A concise and consistent implementation of the policy should be adhered to by all FDA Reviewing Divisions. This approach would go a long way in fostering the goals of efficiency and accuracy of SPL eSubmissions. If there are official differences in the requirements for submission to the different Reviewing Divisions within FDA, this fact should be disseminated via a formal communication.*
- *When will the FDA be able to receive more than one SPL to the same (A)NDA in the same submission on the same day?*
- *Does OGD have different expectations for SPL than OND regarding eSubmissions for Annual Reports, as opposed to Supplements?*

Should you have any questions or require additional information, please contact the undersigned.

Sincerely,

A handwritten signature in cursive script that reads "Jean Kirkeleit Davis".

Jean Kirkeleit Davis  
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