



Dockets Management Branch  
HFA-305  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

May 16, 2006

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**Docket No. 2006N-0181**

### **Product Stability Data; Notice of Pilot Project**

This correspondence is submitted in response to a Federal Register Notice appearing in the May 16, 2006 Federal Register concerning the provision of stability data in XML format. According to the notice, "Using the data interchange standards and the analytical tools will allow consistent data presentation to the agency and allow a reviewer to more efficiently and consistently display and evaluate product stability data submitted in electronic format." Currently this data is supplied electronically in "pdf" format. According to the notice, "FDA is currently considering the adoption of the standard as a voluntary standard for transmission of stability data in new drug applications, abbreviated new drug applications, investigational new drugs, new animal drug applications, abbreviated new animal drug applications, and investigational new animal drugs."

On behalf of our clients, Cornerstone Regulatory, has been asked to write in opposition to the proposed program unless the program plans to incorporate a number of changes in its potential direction. These comments are made based on previous Agency experience with XML formats and projects. We are requesting that the Agency incorporate these suggestions to insure that this project which consumes Agency resources is directed to the entire regulated community and can be adopted by the regulated without additional expense.

1. If the Agency goal is a consistent presentation of stability data, this can be done without XML documents. pdf documents can be formatted to appear in any content format so there is no reason to proceed to an XML format for a consistent presentation format. If the Agency intends to do more with the data and needs the XML format to perform that work, the Agency notice should state those reasons so the regulated community can respond to the Agency's intended use.

2. pdf documents can be produced from a variety of programs and yet retain the ability to search, copy, and paste information between documents and programs. XML does NOT have that same broad appeal and functionality between programs. Indeed the Agency in past projects (SPL product labeling) has altered the header information and tags to such an extent that if the users current software program was able to export to XML that necessary additional header and tag information could not be incorporated. This caused the need to purchase and learn new software programs at an additional expense to regulated companies. Again if the intent is to present data in a consistent format, inclusion of additional header and tag information should be unnecessary.

3. Even when software is available to perform XML export many times it is not capable of being used because the Agency prefers or requires elements to be included that are NOT cross platform. Therefore the Agency dictates that a Microsoft platform is used rather than

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a Linux or Macintosh compatible program be used. This dictates additional hardware and software costs on to the regulated community.

4. Many of the current legacy programs used by the regulated industry to provide stability data are not capable of exporting to XML format. As these systems were validated according to 21 CFR Part 11 requirements forcing companies to convert and validate additional software produces a incredible burden on a regulated industry, currently under pressure to reduce costs.

5. Many smaller generic companies use simple spreadsheet programs to produce and present the stability data in the current format recommended. Indeed the Agency has highlighted in presentations the use of spreadsheet programs to present stability data in a format consistent with Agency expectations. If the Agency intention is to provide a consistent format for review the current system can be used without an XML format. These small companies do not have the capabilities or resources to change their stability tracking and data management systems to an XML format.

6. Finally some of our clients prepare and manage their stability data from a database application (FileMaker Pro) which is cross platform. Their concern is that all stability presentations by the Agency appear to utilize a spreadsheet approach. They are concerned that the XML format that the Agency may adopt would force them to convert their data to a different format (e.g. spreadsheet) which they feel is inferior to their current data management system.

Cornerstone Regulatory hopes the Agency will take into account the concerns that our clients have expressed and incorporate their concerns into the program early enough to prevent additional costs and resource expenses by their companies.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Walter G. Jump", is written over a circular stamp or seal that is partially obscured by the signature.

Walter G. Jump, Pharm.D.  
President

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