



FDA Public Hearing: Electronic Submission of Regulatory Information

December 18, 2006; Docket No. 2006N-0464

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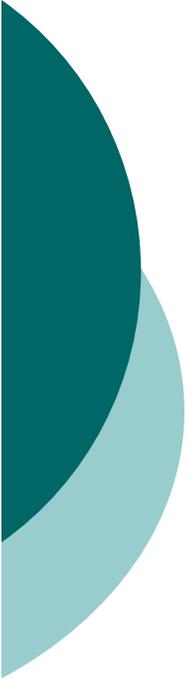
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Issue 1: Transition From Paper Submissions to Electronic Submissions

- The goal is laudable. However, there must be recognition that the tasks involved in the transition are daunting, especially for smaller companies:
 - training
 - installation of a document management system
 - electronic software
 - qualified vendors with appropriate training, software, systems
 - similar issues for suppliers (excipients, APIs, etc.) and for CROs



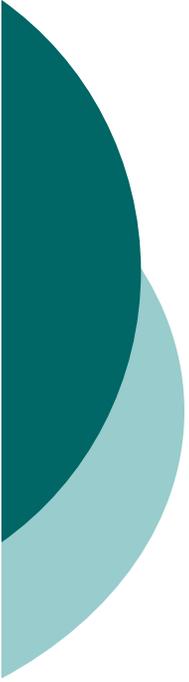
Issue 1: Transition From Paper Submissions to Electronic Submissions

- Other elements to consider
 - large capital investment
 - Additional employees and IT consultants, typically highly skilled and highly paid
 - Cultural shift
 - Difficulties more acute for studies outsourced globally, drug master files, and technical documents
 - Benefits will be in the future, not immediate
 - Need for universally acceptable electronic standards, software data format, and tools



Issue 1: Transition From Paper Submissions to Electronic Submissions

- January 2008 – We understand that the agency might be considering this time frame for transition to electronic submissions.
- We are concerned that this time frame would not allow sufficient time for small and mid-sized companies that rely on outside vendors/suppliers in preparing submissions, or elements of submissions, to convert to a completely electronic medium.



Transition From Paper Submissions to Electronic Submissions (cont.)

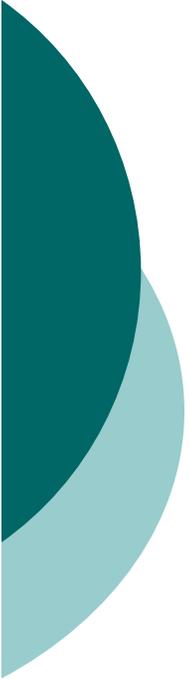
- The agency should note that the cost for achieving electronic submission capabilities is much higher and more burdensome for small and mid-sized companies.



Transition From Paper Submissions to Electronic Submissions (cont.)

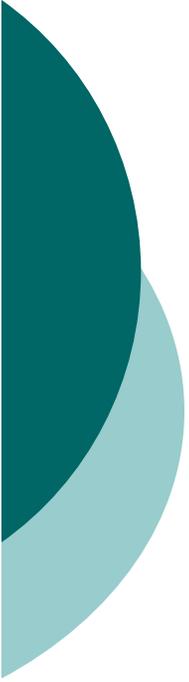
- In addition, for submissions that are already in-progress, outside vendors/suppliers must scan or convert paper materials into electronic files.

→ This is both time consuming and costly.



Issue 2: Time

- Smaller companies that rely on outside vendors/suppliers in preparing submissions will need ample time to:
 - Hire consultants to select appropriate electronic submission software;
 - Coordinate with outside vendors and suppliers to ensure software compatibility; and
 - Roll-out the new software and work out any bugsbefore submission preparation can begin.



Time (cont.)

- Further time delays could occur if outside vendors/suppliers are unable to roll-out new software on the same schedule.
- Some vendors/suppliers may elect not to participate in the transition, which could create delays for sponsors.



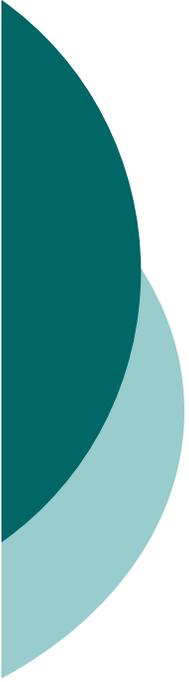
Time (cont.)

- The implementation date (or recommended implementation date) should be **no sooner than three years after the date on which the agency issues a final rule or final guidance on electronic submissions.**



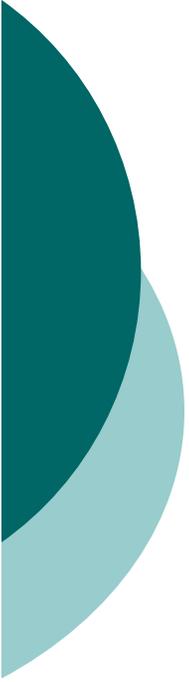
Issue 3: Implementation

- The agency must allow for ample implementation time for an all-electronic submission system.
- There should be a built-in phase-in period, during the 3 year period, for which the agency will continue accepting paper submissions to accommodate in-progress submissions.



Implementation (cont.)

- However, the agency must ensure that equal treatment is accorded to the paper submissions that it receives during any such phase-in period.



Implementation (cont.)

- Finally, the agency must ensure that the electronic submissions initiative does not become a vehicle for requesting companies to include additional information or data in electronic submissions beyond that which is legally required.



Questions for the Agency to Consider...



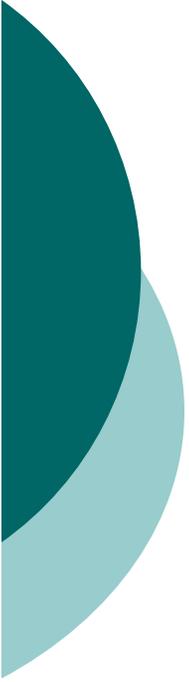
Questions to Consider...

- Will Part 11 be re-examined in an effort to adopt uniform software or systems for submissions, recordkeeping, and signatures?
 - Uniformity can ensure efficiency by streamlining internal processes.



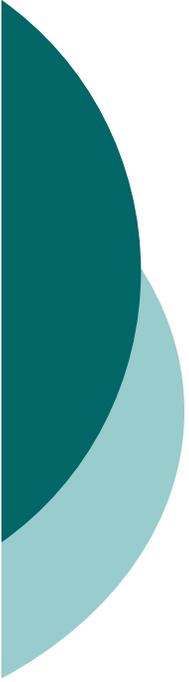
Questions to Consider (cont.)

- What regulatory mechanism will FDA use to adopt a position on electronic submissions?
 - Will FDA initiate a proposed rulemaking or draft guidance?
 - Developing a requirement rather than a recommendation is important to ensure equal treatment and priority of submissions.
 - What impact will this initiative, and the transition period, have on the “first-in, first-reviewed” policy and Paragraph IV certifications?



Questions to Consider (cont.)

- What electronic submission procedures or requirements, if any, have foreign regulatory bodies adopted?
 - FDA should consider the effect that any electronic submission requirements or procedures that it adopts will have on companies who also market overseas.



Thank you

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