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Bridgewater, New Jersey 08807  
July 9, 2004

Mr. Joseph C. Famulare  
Center for Drug Evaluation and Research  
Food and Drug Administration  
11919 Rockville Pike  
Rockville, MD 20852

**Reference Docket No. 2004N – 0133**

Dear Mr. Famulare:

Thank you for the opportunity to provide comments on electronic records and signatures regulations. My comments are related to the definition of electronic records, and the importance of that definition in making the scope of the rule clear and its enforcement consistent.

When Part 11 was originally published, the definition of electronic record was unnecessarily broad, essentially including all digital data related in any way to FDA regulations. Under the new guidance, the definition of electronic record is narrower, but now depends on the business practices and interpretations of each company. This approach also has its problems.

The vast majority of regulated computer systems are not developed by healthcare companies, but by third-party suppliers who often have very limited software engineering staffs. With each regulated company presenting its own definition of electronic records, these suppliers will find it very difficult to develop a single system that satisfies all, and will probably resort to one of two alternatives:

1. Developing customized systems for each client. This will have the effect of decreasing software quality due to the need to develop, test and maintain many different versions.
2. Attempting to develop a single, one-size-fits-all system with a very conservative compliance approach. This will have the effect of imposing unnecessarily strict controls and limiting innovation, as they try to err on the safe side.

Neither of these choices serves the public in terms of increased safety or reduced cost.

My suggestion is that, along with industry's assistance, FDA develop a baseline list of records (or record types) that will be considered electronic records regardless of business practices, and include this in the revised rule. This step will promote a consistent standard and at the same time allow system developers to focus on real innovations that provide a compliance and business benefit, rather than having to continually adapt their system to a new client's definition of electronic records.

If electronic records and signatures are an area that FDA wants to regulate (and I believe it should), then it is important that the agency define what is being regulated in reasonable detail.



While it is probably not possible to define every possible record in advance, the current definition as expressed in recent guidance is far too open-ended and subjective to be useful.

Thank you for the opportunity to provide these comments as FDA contemplates revision of Part 11.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey A. Beck". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Jeffrey A. Beck  
Manager, Quality Engineering  
Pharmaceutical Sourcing Group - Americas  
A division of Ortho-McNeil Pharmaceutical