

# Bristol-Myers Squibb Pharmaceutical Research Institute

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November 8, 2002

**Dockets Management Branch  
Food and Drug Administration, HFA-305  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852**

**Re: Docket No. 00D-1539; Draft Guidance, Draft Guidance for Industry; 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records [67 Federal Register 56848, (September 5, 2002)]**

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2001 alone, Bristol-Myers Squibb dedicated \$2.1 billion for pharmaceutical research and development activities. The company has nearly 6,000 scientists and doctors committed to discover and develop best-in-class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on this FDA draft guidance on Electronic Records; Electronic Signatures, Maintenance of Electronic Records.

## **Summary of BMS Comments on Proposal**

We commend the U.S. FDA for taking a leadership role in developing standards for acceptance of electronic records and signatures. The use of electronic records and signatures is beneficial to both industry and FDA. We further commend the agency in its work to develop this guidance. In general, Bristol-Myers Squibb found the guidance to provide useful approaches to maintaining the quality and compliance of electronic records over their required retention period. Storing backups of electronic records in a location separate from the primary location is excellent guidance. Recognition by the agency of unavoidable losses or changes in migrated data that do not diminish the ability to preserve and present information demonstrates a practical and realistic understanding of the process.

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We do, however, have a few recommendations that may improve the guidance document and these are listed below.

### **General Comments**

We agree with the objective stated in section 5, requiring individuals to “accurately and readily retrieve and use the information that was originally intended to be preserved and presented”. Being able to sort or perform searches to help present and trend information will aid in the ability to present and trend historical data. However, we would not recommend the reprocessing of data that has been reviewed and approved. The data should be protected so that further processing cannot occur in order to adequately preserve the integrity of the approved information. In most cases, processing archived information is an action we do not perform, whether electronically or on paper. Suggesting that firms maintain the ability to reprocess data could present a risk to data integrity.

We recommend the replacement of the use of the phrase “process an electronic record” with “preserve and protect an electronic record”. Additionally, under section 5.5, we recommend the elimination of the term “manipulate”. We do not manipulate previously reviewed and approved retained data and information.

### **Section 5.4 Electronic Records Should Be Stored Under Appropriate Environmental Conditions.**

Monitoring conditions under which electronic records are stored implies these conditions would need to be recorded to verify monitoring has occurred. We agree that environments should be maintained, however we recommend expectations to monitor the environment be reconsidered.

### **5.6 Copying Process Should Produce Accurate and Complete Copies**

The draft guidance states that “A copy process that does not implement such a built-in error mechanism to prevent making an inaccurate or incomplete copy should be validated”. For copy processes that do not contain built in verification mechanisms, in addition to validation, some form of a verification process should be instituted. We recommend the last word in the last sentence of this section be changed from “validated” to “checked or verified”.

### **6.1 Time Capsule Approach**

The guidance states that the time capsule approach to long-term maintenance of electronic records may have limited practicality. We believe the objective of this approach is to maintain the ability to reprocess data over the entire retention period, an action we do not normally perform. We recommend that this section of the draft guidance be eliminated and replaced with an alternative approach, which allows for the continued use of an application to access and/or retrieve data only.

## **6.2 The Electronic Records Migration Approach**

Maintaining old data and the ability to process it, after a validated migration process is complete appears to be an unnecessarily burdensome expectation. Validation of the migrated data and the process for migrating it should be considered sufficient. We recommend the elimination of agency expectations for maintaining old data that has been migrated.

### **6.2.1.3 Electronic Record Integrity Should Be Preserved**

Generally data migration activities are automated, not created by operator action. Additionally, the migrated data is not considered to be created, modified or deleted in the context of 21 CFR Part 11. In our opinion adding a second “create” transaction as part of a migrated data activity may add confusion to the audit trail events. In light of this, we recommend the audit trailing of migration actions be eliminated from the guidance document.

### **6.2.1.5 Unavoidable Differences**

Further clarification regarding the use of third parties for digital signature should be provided. The phrase “from outside the organization that has some responsibility for the electronic record” seems confusing and possibly contradictory. A process could be defined whereby “in house” personnel are used for such activity. It seems that in order to have some responsibility for the record, only in house personnel could be used. We recommend that the term “independent party” be substituted for “trusted third party.”

We commend the agency’s recognition of unavoidable losses and changes in certain information during migration that do not diminish the reliability of the information. However, it appears contradictory to add a statement that this is unacceptable for information specifically mandated by predicate rules. We recommend elimination of the two sentences in the first paragraph starting with “It should be clear...”.

### **Additions to Glossary of Terms Guidance (Docket No: 00D-1543)**

Consideration should be given to adding the following terms with their definitions to the Part 11 Guidance Glossary of Terms:

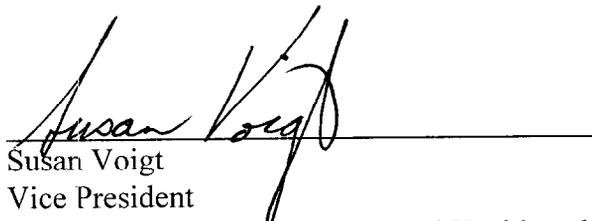
- Reconstruct Events
- Flash memory device
- Trusted Third Party

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,



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Information and Knowledge Management



Susan Voigt  
Vice President  
Corporate Quality, Environmental Health and Safety



Laurie Smaldone, M.D.  
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