



Amgen  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799  
805.447.1000  
[www.amgen.com](http://www.amgen.com)

December 2, 2002

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

Reference: Docket Number 00D-1539  
Draft "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures  
Maintenance of Electronic Records" August 2002

Dear Sir/Madam,

Amgen Inc. appreciates the opportunity to provide comments on the above referenced Draft  
Guidance for Industry.

Although the August 2002 Draft "Guidance for Industry 21 CFR Part 11; Electronic Records;  
Electronic Signatures Maintenance of Electronic Records" does provide additional information  
and guidance to industry regarding compliance with the maintenance of electronic record  
requirements of 21 CFR Part 11, additional clarification is requested.

Amgen's specific comments are as follows:

1. Documents and reports often constitute the "human readable" electronic record that is meaningful to both the operator and inspector. With current technology, conversion of documents and reports to technology neutral formats, such as PDF (Adobe Portable Document Format), provides a ready mechanism creating accurate reproductions of the electronic record. These reproductions are created at the time of use of the electronic records and are useful for ensuring the accuracy, integrity, and long-term accessibility of such electronic records. These characteristics are realized, however, at the cost of processing capabilities and detachment from the underlying data. We recommend the use of technology neutral data formats for report/document preservation be addressed in the guidance.
2. Design decisions regarding the electronic record formats that a system will support must be made early in the system development lifecycle. We recommend additional guidance regarding the data formats considered acceptable, similar to the guidance given for data formats suitable for electronic submissions.
3. It is common practice to retire software and hardware as it becomes obsolete and replace systems with current technology. Functional capabilities for creation and processing of electronic-records may vary in the replacement computer systems or may even be lost completely. However, as long as the functional capabilities of the replacement system are sufficient to meet predicate rule requirements (and all of the

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predicate rules that applied to the original system are still in effect), then the functional capabilities of the replacement system should be sufficient to meet the on-going requirements for electronic records migrated to the replacement system. We recommend this issue be clarified in the guidance.

4. During the retention period of an electronic record, it will enter the inactive phase of its life cycle, where manipulation of the record is not an allowed transaction. Section 5.5 does not address this situation when discussing processing of information over the entire records retention period. To a large degree, the integrity of electronic records is ensured during long-term retention by disabling processing capabilities that allow electronic records to be manipulated or altered. We recommend this issue be clarified in the guidance.
5. The draft guidance does not address the approach to ensuring the trustworthiness of electronically signed records over time that has been adopted by the National Archives and Records Administration, NARA, (Records Management Guidance for Agencies Implementing Electronic Signature Technologies, October 18, 2000, Section 4.3). This approach consists of maintaining "adequate documentation of the records' validity, such as trust verification records, gathered at or near the time of record signing." Since the NARA has adopted this approach for archival storage of Federal records, we recommend the guidance address the FDA's evaluation of this approach and its suitability for the maintenance of electronically signed records within the scope of 21 CFR Part 11.
6. The first paragraph of Section 6.2.1.5 states, in part, that information losses or modifications in migrated electronic records must be "...properly accounted for, and explained in either the migrated record or readily available electronic documentation." We request clarification as to why migration documentation must be kept electronically.

Thank you again for the opportunity to provide comments on the agency's draft guidance documents. If you have any questions, feel free to contact me at (805) 447-6203.

Sincerely,



Dawn Viveash  
Vice President Regulatory Affairs