

Aventis Pharmaceuticals



December 20, 2001

Via fax and UPS

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

Re: Docket No. 00N-1543

Draft Guidance: 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms [66 FR 48886, September 24, 2001]

Dear Sir/Madam:

Aventis Pharmaceuticals would like to thank you for the opportunity to comment on the above-referenced Draft Guidance entitled "21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms". The document defines terms that will be used in other FDA guidance documents about Part 11. We offer the following comments/clarification for your consideration.

In section 3. **DEFINITIONS** (page 4), the definition of "*Computer Systems Validation*" is stated in this guidance as "*Confirmation by examination and provision of objective evidence that computer system specifications conform to user needs and intended uses, and that all requirements can be consistently fulfilled*".

In the past, the FDA has defined validation as follows:

- in the **Guideline General principles of process validation** published in May 1987, the FDA has defined "*Process Validation*" as "*establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics*";

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- in the *Guidance for Industry Computerized systems used for clinical trials* published in April 1999, the FDA has defined “Software Validation” as “confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through the software can be consistently fulfilled. For the purposes of this document, design level validation is that portion of the software validation that takes place in parts of the software life cycle before the software is delivered to the end user”.

These seem similar on the surface, but the new definition requires that we “confirm” the evidence examined/provided for review whereas the definition for process validation just asked that the evidence be “established and documented”.

Some GXP systems may impact process, computer, and software validation activities. It is therefore important to ensure that the definitions provided in various guidance documents relating to validation are compatible, and thereby avoid potential conflicts.

On behalf of Aventis Pharmaceuticals we appreciate the opportunity to comment on 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms and thank you for your consideration.

Sincerely,



Steve Caffè, MD
Vice President, Head GRAMS – North America
Global Regulatory Approvals and Marketing Support