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

Subject: **Docket No. 00D-1538**
Draft "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation."

Docket No. 00N-1543
Draft "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms."

04 December, 2001

Dear Sir/Madam:

Thank you for the opportunity to comment on the *Draft "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation"* and the *Draft "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms"* published in the Federal Register on September 24, 2001. Outlined below are Genzyme's comments for your consideration.

1. *Section 6.1.2 Software Structural Integrity* of the Validation Guidance states that users should evaluate a supplier's software development activities to determine its conformance to contemporary standards preferably through an audit. Commercial software vendors do not allow examination of their source code to protect proprietary interests. These same concerns may prevent commercial vendors from allowing audits of their development activities. The Pharmaceutical and Biotech Industry is not the primary market for these vendors, and software developers may have little incentive to reveal source codes or allow audits. Unfortunately, there are limited products available in the current market and the Industry may not be able to choose a more compliant or responsive vendor. We would appreciate further guidance in this area.

2. Please provide further guidance on prototyping as related to validation. Prototyping is a highly fluid and iterative process, and there might be an occasion where one iteration is deemed sufficient to be moved on to final product.

3. Many companies have networks that integrate process (e.g., GMP or GCP) systems and business systems (e.g., financial and sales records unrelated to FDA requirements)). We would appreciate your guidance on how to restrict validation to those activities that require validation. For example, in a Materials Resource Planning (MRP) System, financial records do not require validation, while other activities (such as validating transactions that identify materials as *quarantined* or *released*) do need to be validated. Is there an acceptable way of "partitioning off" these areas for validation?

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4. Please describe the type of validation FDA would be seeking for Virtual Private Networks (VPNs), which are becoming more common as security measures are heightened.

5. FDA makes reference to "off-the-shelf (OTS) software." We believe that there is a distinction between commercial off-the-shelf software that is sold for profit, and open-source software, which is not sold, there is no single entity ownership of intellectual property rights, and no specific development under a quality umbrella. There may be times when a company is compelled to use open-source software. We ask FDA to make this distinction in its glossary, and provide guidance as to how a company would validate open-source software.

6. We respectfully suggest that FDA add the following to its glossary to standardize terminology.

   6.1. Black and White Box Testing. Although defined in the Validation document, we feel it would be helpful to have all terms related to validation in a central place.
   6.2. Prototyping
   6.3. Virtual Private Networks
   6.4. Public Key Infrastructure

Genzyme appreciates the opportunity to comment on the Draft "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation as well as the Draft "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms." Please contact me at (617) 374-7275 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,

Robert E. Yocher
Vice President
Regulatory Affairs