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December 21, 2001

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, room 1061
Rockville, MD 20852
Docket Number: 00D-1538

To Whom it May Concern,

I hereby submit the following comments concerning the Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures Validation.

Section 1. Purpose

While the intended purpose is to provide guidance to the industry and to assist individuals in compliance with the regulations, the guidance itself is vague. More detailed information would be helpful, particularly as to how the Part 11 regulations pertain to each of the individual predicate rules.

Section 5.1 System Requirements Specifications

The guidance suggests that additional factors that should be considered when validating computer systems should include scanning processes. Does this require that all scanners be assessed? Some scanners are used to scan printed copies of chromatograms into reports. It would seem excessive to validate these scanners.

Section 5.8 Change Control

Clarification is needed concerning regression analysis and regression testing. Is the guidance suggesting that any time additional software is added or changes are made to a computer system or existing software program, that all systems currently validated need to be revalidated? This would seem excessive.

Section 6.1.3 Functional Testing Software

The guidance states that software testing should cover all the intended functions the end user will use. Does this mean every application must be validated before use? It would be impossible to test every function for systems such as Excel and Word.

Section 6.2.1 Internet Validation

Does validation of the destination computing system need to be validated by the originating party? This would be difficult to conduct and control.

Sincerely,

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Director of Laboratory Operations

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