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April 24, 2003

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

RE: Docket No. 03D-0060, 99D-1458, 00D-1538, 00D1542 and 00D-1539;Draft Guidance for Industry on Part 11, Electronic Records, Electronic Signatures – Scope and Application

Dear Madam or Sir:

Becton, Dickinson and Company (BD) appreciates the opportunity to submit these comments in response to the Food and Drug Administration's (FDA's) Draft Guidance on Part 11 Electronic Records, Electronic Signatures – Scope and Application [Federal Register, February 25, 2003].

BD supports the FDA's efforts to clarify the requirements of 21 CFR Part 11 and has thus identified five areas where we believe further clarification is necessary.

1. The Guidance for Industry on "Computerized Systems Used in Clinical Trials" (April 1999) and "General Principles of Software Validation" (January 2002) both contain numerous references to 21 CFR Part 11 and its technical requirements, some of which are now subject to enforcement discretion. In connection with this effort to describe the scope and application 21 CFR Part 11, BD requests that the FDA also re-examine these publications.

2. The Draft Guidance document states on lines 126 through 134 the intention to "enforce all other provisions of Part 11 including... requirements related to electronic signatures (e.g., §§ 11.50...)" Further, 21 CFR 11.50(b) states the required elements of signature manifestations "shall be subject to the same controls as for electronic records." Therefore we request clarification on the FDA's intentions to enforce full compliance with Part 11 for systems that maintain electronic records which contain electronic signatures.

3. The FDA calls for "a justified and documented risk assessment" when manufacturers make decisions regarding validation, audit trails, and record

99D-1458 C19

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retention. Clarification should be made as to whether the FDA recommends any specific standards or methods for conducting these assessments, or for expectations of the content and form of these assessments.

4. The Draft Guidance document states in line 41 through 44, "we intend to exercise enforcement discretion and will not normally take regulatory action to enforce Part 11 with regard to systems that were operational before August 20, 1997." Please detail at what point the FDA would take regulatory action to enforce Part 11 with regards to systems that were operational before August 20, 1997, and what changes to a electronic system would no longer define the electronic system a "Legacy System."

5. Lines 252 and 253 state, "Producing copies of records held in common portable formats where records are kept in these formats." Please expound as to if this indicates that a company would provide the FDA with electronic copies of the records along with a copy of the program software. A further clarification of "portable formats" would be very beneficial. For example, please explain if included in this definition are view-only formats or common, recognized standards in their native format such as Microsoft Access and Oracle databases, spreadsheets and word-processing files, common CAD and graphic file formats, etc.

In sum, BD appreciates the FDA's effort to provide guidance on 21 CFR Part 11, however feels that more specific clarification is necessary to achieve a sufficient level of compliance. We are grateful for the opportunity to comment on the Draft Guidance and we are optimistic that the FDA will address these issues.

Sincerely,

Patricia B. Shrader, Esq.
Vice President
Corporate Regulatory Affairs and Compliance