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December 27, 2004

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

RE: Docket No. 2004D-0440; Guidance for Industry on Computerized Systems Used in Clinical Trials

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) Guidance for Industry on Computerized Systems Used in Clinical Trials [Federal Register, October 4, 2004 (Volume 69, Number 191)].

BD supports the FDA's efforts to update this Guidance document and would like to submit the following comments:

A. General Comment of the overall document:

Response: BD agrees with the intent of this Guidance document, which is to provide the industry general direction rather than specific requirements. BD also agrees with the emphasis throughout the Guidance document on applying risk assessment to determine appropriate design, control and validation for each individual application. This is consistent with the agency's current thinking and with other guidance documents, which focus on the use of a risk-based approach.

B. Individual Comments:

1. *Line 256 "We recommend that prompts, flags, or other help features be incorporated into the computerized system to encourage consistent use of clinical terminology and to alert the user to data that are out of acceptable range."*

Response: BD would like to have further clarification on the above statement. BD feels it is acceptable if a computerized system has internal design (e.g. algorithm, check) to verify the data, but it does not inform the users at the time of data entry. In other words, it should be acceptable if data verification is performed at a later time after data entry.

2. *Line 307 "We recommend that a cumulative record be available that indicates, for any point in time, the names of authorized personnel, their titles, and a description of their*

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access privileges. We recommend that the record be kept in the study documentation, accessible at the site."

Response: BD feels that this statement is rather prescriptive and goes above and beyond the 21 CFR Part 11 regulation. We recommend that it should refer to the Access Control requirement of the 21 CFR Part 11 regulation rather than describe another duplicate or potentially conflicting requirement regarding the access control to the system.

3. *Line 401 "In the case of off-the-shelf software, we recommend that the following be available to the Agency on request: A written **design specification** that describes what the software is intended to do and how it is intended to do it;"*

Response: BD feels that further clarification is needed for when a "design specification" is required for off-the-shelf software. A design specification is generally understood by the industry (e.g. GAMP4) and is also defined in the FDA's guidance document "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" as a design-level document describing how the system is designed to meet the system requirements; and thus, this document is generally written by the system developer/vendor. Therefore, for an off-the-shelf software, where its source code is not modified after purchase, the user does not write a design specification. In this case, the user writes a User Requirements Specification or a System Requirements Specification describing the intended use of the purchased system.

In sum, BD appreciates the FDA's effort to provide clarification Guidance for Industry on Computerized Systems Used in Clinical Trials, however feels that more specific clarification is necessary to achieve a sufficient level of compliance. BD is grateful for the opportunity to comment on the Regulation and remains optimistic that the FDA will address these issues.

Sincerely,

A handwritten signature in black ink that reads "Patricia B. Shrader" with a stylized flourish at the end.

Patricia B. Shrader, Esq.
Vice President
Corporate Regulatory, Public Policy and
Communication