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July 16, 2004

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

RE: Docket No. 2004N-0133; Electronic Record; Electronic Signatures; Public Meeting

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) Electronic Record; Electronic Signatures; Public Meeting [Federal Register, April 4, 2004 (Volume 69, Number 68)].

BD supports the FDA's efforts to clarify the requirements of 21 CFR Part 11 and has thus responded to the questions that FDA posed regarding 21 CFR Part 11.

A. Part 11 Subpart A – General Provisions

1. *“whether part 11 should be revised to implement the narrow interpretation described in the guidance.”*

Response: BD agrees with the narrowed scope in the part 11 guidance document and believe that it should be applied to the regulation. BD also feels that the narrowed scope in the guidance document needs to be applied in the same context as the guidance document; that is, the intent of the regulation to protect the integrity of electronic records and electronic signatures. The manner in which 21 CFR Part 11 should be implemented should be based on the risk involved to the patient safety and product effectiveness. Each individual application would have to be assessed and the necessary controls implemented on that application based on the risk to the patient.

2. *“whether revisions to definitions in part 11 would help clarify a narrow approach and suggestions for any such revisions.”*

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Response: BD believes that the definitions are still appropriate in the context of the narrowed scope and does not think that any changes need to be made at this time.

3. *“the need for clarification in part 11 regarding which records are required by predicate rules and are therefore required to be part 11 complaint?”*

Response: BD believes that further clarification is needed in part 11 regarding which records are required by predicate rules.

B. Part 11 Subpart B – Electronic Records

1. *“whether there are other areas of part 11 that should incorporate the concept of a risk-based approach, detailed in the part 11 guidance”*

Response: BD believes that the following areas of part 11 should incorporate a risk-based approach: 1) Validation, 2) Accurate and complete copies, 3) Protection, 4) System Access, 5) Audit trails, 6) Operational System Checks, 7) Authority checks, 8) Device checks, 9) Training, 10) Controls over system documentation, 11) Revision and Change Control Procedures, and 12) Controls for open systems.

2. *“Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled?”*

Response: The regulation should address the minimum requirements for compliance. The regulation should not go into the specifics of how to implement part 11. Implementation of part 11 may be more appropriate in a guidance document. In some cases the regulation states examples of how to achieve compliance, i.e. audit trails. Audit trails are just one means of achieving the requirement for showing what has been changed, who changed it, when they changed it, and why it was changed. The examples could be mis-interpreted as the minimum requirement.

3. *“Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements?”*

Response: BD believes that those documents submitted to the FDA should be separate from electronic records maintained to satisfy predicate rule requirements.

4. *“Should part 11 continue to differentiate between open systems and closed systems?”*



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Response: Team Response: BD believes that the differentiation between open and closed systems should remain. However BD does believe that the examples of controls in 11.30 should be removed, because they go beyond the minimum requirements of the regulation and get into implementation; e.g. encryption may be seen as the minimum requirement for open system controls.

Individual Comments in subpart B

1. *“Should we retain the validation provision under Sec. 11.10(b) required to ensure that a system meets predicate rule requirements for validation?”*

Response: As a medical device company, BD does not see the need to include validation within the part 11 regulation, because validation is already a requirement of part 820.70 (i). BD does, however, understand the need to retain the requirement for validation in part 11 if it is not covered for other FDA regulated industries.

2. *“What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency?”*

Response: BD does not see the need to include record copying and record retention requirements within the part 11 regulation, because record copying and record retention requirements are already a requirement of part 820.180. There may, however, be a need to retain the requirement for record copying and record retention in part 11 if it is not covered for other FDA regulated industries.

3. *“Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?”*

Response: BD believes that adding the requirements to deter, prevent, and document unauthorized record creation, modification, and deletion to the audit trail requirements would be redundant, because they are already covered in part 11.10 (d) and (g).

4. *“should part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system’s software and hardware?”*

Response: BD does not see the need to include concepts such as configuration and document management within the part 11 regulation, because validation is already a requirement of part 820.70 (i), as well as being detailed in the General Principles of Software Validation: Final Guidance for Industry and FDA. BD



does, however, understand the need to retain these requirements in part 11 if they are not covered for other FDA regulated industries.

C. Part 11 Subpart C – Electronic Signatures

“Should part 11 address investigations and followup when these security breaches occur?”

Response: BD believes that this does not need to be added to the regulation, because this is something that should be addressed during the risk assessment of the system. The standard industry practice is to investigate any attempts to breach the system and correct any issues that may be found, as appropriate. This specific issue could be covered in a guidance document.

D. Additional Questions for Comment

2. *“Is there a need to clarify in part 11 which records are required by predicate rules where those records are not specifically identified in predicate rules?”*

Response: BD believes that further clarification is needed in part 11 regarding which records are required by predicate rules and which are required to be part 11 compliant.

5. *“What risk-based approaches would help to ensure that electronic records have the appropriate levels of integrity and authenticity elements and that electronic signatures are legally binding and authentic?”*

Response: BD does not recommend any specific risk assessment tools, but does recommend that companies follow the approach described in ISO 14971.

6. *“What are the stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997?”*

Response: BD feels that FDA should grandfather all legacy systems.

Furthermore, companies should conduct risk assessments for those legacy systems and specify a system retirement plans for those legacy systems. The speed by which companies replace legacy systems would be based on the severity of the risk involved. For instance, if a legacy system was found to be a high risk and the retirement plan indicated that the legacy system was not scheduled to be retired for several years, the company would put the necessary controls in place to reduce the risk to the patient.

If the FDA feels that more is needed, then legacy systems should be grandfathered until which time significant changes have been made to the system. The FDA needs to further define what “significant” means. For instance, if a change is made to an operating system, but it does not affect the application that is being



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used in the operating system, would 21 CFR Part 11 then apply? Further clarification is needed on this issue.

7. *“Should part 11 address record conversion?”*

Response: BD does not recommend that part 11 itself should address record conversion. This topic would be better addressed in a guidance document or in other regulation. However, FDA should clarify the permissibility of converting paper records to electronic format. Such clarification could be made either in 21 CFR 820.180 (for the medical device industry specifically), or in an agency-wide guidance document. The use of accurate and complete reproductions is explicitly permitted by regulation in the pharmaceutical industry with 21 CFR 211.180(d), and was also permitted in 21 CFR 820.180(b) prior to the 1996 revision of the Quality System Regulation. Compliance Policy Guides and Investigations Operations Manual continue to support the use of microfiche and microfilm reproductions in place of original records, but FDA’s stance on the use of electronic reproductions (e.g., a paper record scanned and converted to Adobe Acrobat format) is unclear.

8. *“Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?”*

Response: The regulation should be reviewed to ensure that the requirements are clearly stated in their most fundamental form in order to keep them as independent from the actual technology used to implement them as possible. This will accommodate the adoption of new technologies that fulfill the requirements as they become available and affordable.

FDA should consider writing the regulation in such a way that the requirements for signatures and records are independent of the technology used, i.e. paper, electronic, or future technology. The difference will be in how industry implements the regulation.

For example making changes to a record should require that the original data not be obscured, and include identification of the individual making the change, and the date the change was made. This should be the requirement for any changes to a record, independent of the technology used to make the change. Currently this requirement exists in part 58.130 (e). Generally, industry has implemented this requirement by using one line through the original data, initial, and data for paper records. For electronic records, industry may implement the requirement by using audit trails. A requirement for signatures and records that is independent of the technology would help clarify current requirements and how they might apply to

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future technology. Means by which to achieve compliance to the requirements for specific technology could be covered in guidance documents.

In sum, BD appreciates the FDA's effort to provide clarification on 21 CFR Part 11, 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,

Christine Seiner
For Pat Shrader

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