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July 9, 2004

Division of Dockets Management (HFA–305)
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

***Re: Docket No. 2004N–0133 - Electronic Record; Electronic Signatures; Public Meeting***

Dear Sir/Madam:

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the attached comments to this docket. AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,100 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world.

AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

We believe that, at least for the medical device industry, FDA should withdraw Part 11 and permit the Quality System Regulation (21 CFR 820) to govern the industry's creation, use and maintenance of electronic records and signatures. We believe that Part 820 adequately provides for the use and control of electronic records and signatures. Attachment A is a table showing how we believe the various sections of Part 820 address the Part 11 requirements.

Should FDA choose not to withdraw the regulation, we believe that Part 11 should be pared down significantly. The resulting regulation should account for the philosophy expressed in the recent Scope guidance. Most significantly, it should clarify that scope is limited to only those records required by predicate rules, and it should permit the manufacturer to apply risk management to determine which Part 11 controls to apply to any system and the extent to which those controls are necessary for each system.

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Simply stated, a "new" Part 11 should be a limited regulation that provides a framework to guide manufacturers in the application of predicate rules to electronic records and signatures. Ideally, the regulation would point the user to the record keeping requirements in predicate rules with little in the way of prescriptive requirements. The agency could then describe its expectations further by issuing guidance. Attachment B contains specific comments responding to the questions FDA posed in the *Federal Register* Notice announcing the public meeting.

We appreciate the opportunity to comment on this important issue. Should you have any questions or require additional information please contact me at 202.434.7230 or bliebler@advamed.org).

Sincerely,

Bernie Liebler
Director
Technology and Regulatory Affairs

## Attachment A - Comparison: Part 11 – Part 820

| Section | 21 CFR 820 - Applicable Section |
|---|---|
| 11.1 | Current QSR regulations (21 CFR Part 820) adequately provides for the use of electronic records and electronic signatures |
| 11.10 | 21 CFR 820.25(b), 820.40, 820.70g.2, 820.80, 820.180 requires adherence to the requirements of this section |
| 11.50 | 21 CFR 820.70i and *General Principles of Software Validation Final Guidance for Industry and FDA Staff* provide sufficient evidance for the requirement. |
| 11.70 | 21 CFR 820.70i and *General Principles of Software Validation Final Guidance for Industry and FDA Staff* and current regulations on electronic signatures provide sufficient evidance for the requirement. |
| 11.100 | Adherence to previously defined prediacte rules will negate the need for this section |
| 11.100 | Expectations defined in *General Principles of Software Validation Final Guidance for Industry and FDA Staff* |
| 11.200 | Expectations defined in *General Principles of Software Validation Final Guidance for Industry and FDA Staff* |
| 11.300 | Expectations defined in *General Principles of Software Validation Final Guidance for Industry and FDA Staff* |

**Attachment B**

## AdvaMed Responses to FDA Questions Contained in Notice of Public Meeting

| Question Section | Question # | Question | Comment/Rationale |
|---|---|---|---|
| Subpart A – General Provisions | 1 | We are interested in comments on FDA's interpretation of the narrow scope of Part 11 as discussed in the Part 11 guidance and whether Part 11 should be revised to implement the narrow interpretation described in the guidance. | We agree with the narrow interpretation of scope in FDA's "Scope and Application" guidance. In regard to records. The guidance states; "...when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be 'using electronic records in lieu of paper records'".<br><br>In addition, we suggest incorporating the concept of risk assessment to narrow further the overall scope of Part 11. While the "Scope and Application" guidance narrows scope around specific Part 11 requirements, we believe it should be allowable to use risk assessment to determine which records are in scope of the entirety of Part 11.<br><br>FDA could resolve much of the confusion surrounding which records fall within the scope of Part 11 by limiting the scope to those records required under the predicate rules. Narrow the regulation to focus on compliance with predicate rules – the company's quality system should clearly define the official record. |
| Subpart A – General Provisions | 2 | We are interested in comments on whether revisions to definitions in Part 11 would help clarify a narrow approach and suggestions for any such revisions. | We suggest definitions be added for legacy systems and predicate rules.<br><br>We also believe that removing both the definitions for and the distinctions between "open" and "closed" systems would be an improvement.<br><br>Finally, definitions should be more closely coordinated with those of similar records in cGMP regulations (Parts 210-211, 820, 600). |
| Subpart A – General Provisions | 3 | We are interested in comments on the need for clarification in Part 11 regarding which records are required by predicate rules and are therefore required to be Part 11 compliant? | There is no need to further clarify the predicate rule requirements. They are well established and understood. Part 11 should be modified to apply only to those records required by the predicate rules. |
| Subpart B – Electronic Records | 1 | We are interested in comments on whether there are other areas of Part 11 that should incorporate the concept of a risk-based approach, detailed in the Part 11 guidance (e.g., those that require operational system and device checks). | The idea of a "risk-based" approach is that the application of the rule and the level of effort applied to compliance should be commensurate with the risk [presented by a faulty record. In other words, risk should determine the level of application of the rule and thus, the subsequent level of effort used. This should apply to the entire regulation. |

**Attachment B**

## AdvaMed Responses to FDA Questions Contained in Notice of Public Meeting

| Question Section | Question # | Question | Comment/Rationale |
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| Subpart B – Electronic Records | 2 | Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled? | Part 11 should refer readers to predicate rules for clarification regarding records required. Then, Part 11 needs only to state that risk management is the appropriate means to determine the actions taken to comply with the predicate rule requirements. |
| Subpart B – Electronic Records | 3 | Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements? | We do not feel separate requirements are necessary for either type of record. FDA should adopt a single, consistent approach to record keeping and maintenance. |
| Subpart B – Electronic Records | 4 | Should Part 11 continue to differentiate between open systems and closed systems? | No, we do not feel Part 11 should differentiate between open and closed systems. Both the definitions and the distinctions should be removed from the rule. The level of security should be based upon the risk to the integrity of the record and its impact on product safety |
| Subpart B – Electronic Records – Individual Ctrls | 1 | Should we retain the validation provision under § 11.10(b) required to ensure that a system meets predicate rule requirements for validation? | No. Because validation is a predicate rule requirement, the inclusion of validation in Part 11 has caused significant confusion on the part of many in industry. As FDA's "Scope and Application" guidance states, "Although persons must still comply with all applicable predicate rule requirements for validation, ... this guidance should not be read to impose any additional requirements for validation."<br><br>The best approach may be for Part 11 to require appropriate validation per predicate rule requirements. |
| Subpart B – Electronic Records – Individual Controls | 2a | Are there any related predicate rule requirements that you believe are necessary to preserve the content and meaning of records with respect to record copying and record retention? | We do not see a need to revise predicate rule requirements for medical devices. The risk should determine the level of safeguards applied. |
| Subpart B – Electronic Records – Individual Controls | 2b | What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency? | Predicate rules (21 CFR 820.180, 211.180, and 211.68) require record integrity and suitability for FDA inspection, review, and copying. There is no need for Part 11 to add to these requirements. |
| Subpart B – Electronic Records – Individual Controls | 3 | Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion? | The current requirements contained in Part 11 provide sufficient protection for records. However, this would be addressed more appropriately as part of security requirements, not audit trails. |
| Subpart B – Electronic Records – Individual Controls | 4 | In light of how technology has developed since Part 11 became effective, should Part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware? | Configuration management is sufficiently provided for in Existing predicate rules and validation guidance adequately address configuration management. Document management is a predicate rule requirement. |

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## AdvaMed Responses to FDA Questions Contained in Notice of Public Meeting

| Question Section | Question # | Question | Comment/Rationale |
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| Subpart C – Electronic Signatures | 1 | Should Part 11 address investigations and follow-up when these security breaches occur? | We feel that Part 11 adequately covers this in subsection 11.300(d). However, the section is too prescriptive, and we suggest removing the phrase "in an immediate and urgent manner" from this subsection. The approach used to detect and report unauthorized use of passwords and/or identification codes should be determined based upon the unique requirements of the system being addressed.<br><br>This subject would best be left to the predicate rules. |
| Additional Questions | 1 | What are the economic ramifications of modifying Part 11 based on the issues raised in this document? | It is too early to determine economic ramifications for issues raised in this document, because there is no clear indication of what the rule will contain. This will be an appropriate and welcome question when FDA publishes a proposed revised regulation. |
| Additional Questions | 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? If so, how could this distinction be made? | Part 11 should apply to records required by predicate rules, which should be the source of the specification |
| Additional Questions | 3 | In what ways can Part 11 discourage innovation? | Part 11 discourages innovation both from a computer system development perspective and from a user's perspective. Part 11 compliance may prevent system vendors from exploring practical applications for technology in a specific market. For example, developers might more quickly supply remote communications and access for remote diagnostics for troubleshooting interventions during manufacturing events and for identifying more quickly deviations from product specifications during manufacturing events, which would allow for better process control, and be more cost effective. However, because of the compliance implications of 21 CFR Part 11, neither vendors nor their customers (the manufacturer) would be willing to invest the time and resources to tackle the unknown. Unknown because we can't predict how the narrow scope of Part 11 will address future technology when we don't know what that is.<br><br>21 CFR Part 11 cannot possibly keep up with the technology changes the computer software/hardware industry is introducing. FDA guidance should be focused on the intent to preserve the integrity of the product manufactured using a system and should not be focused on legitimate technology that could be used to bring better, safer products to market quicker and less costly.<br><br>Finally, the more prescriptive the rule is the more it will discourage the use of new technology. |

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| Additional Questions | 4 | What potential changes to Part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health? | Limit to cover only those records required by the predicate rules. |
| Additional Questions | 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? | The risk management of required records should be an extension of the risk management that is central to medical device quality systems. If the records/signatures system is constructed with the appropriate uses and risks in mind, it will intrinsically provide the appropriate levels of authenticity, security, and integrity. |
| Additional Questions | 6a | What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997? | If the manufacturer follows an appropriate risk-based scheme for determining how to handle specific systems, there should be no need for the "legacy" designation. The risk management scheme will determine when and to what extent systems need to be modified or validated,<br><br>IF FDA adopts the idea of a broadly risk-based system, there will need to be training for investigators to understand how to deal with the various ways that manufacturers may treat systems in use in August 1997. |
| Additional Questions | 6b | Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems? | See our response to 6a. |
| Additional Questions | 7 | Should Part 11 address record conversion? | Predicate rules cover record conversion. Thus, Part 11 needs only to generally address it. Industry should define the methods used to meet the intent of record integrity consistent with FDA's requirements to ensure record validity and traceability. The validation plan for a system should define and cover this. |
| Additional Questions | 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? | The regulation should be stated in performance language so that references to specific technologies are not needed. |