

6 July 2004

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

Dear Sir/Madam:

We are pleased to submit the attached ISPE GAMP response to the FDA Part 11 revisions. Our response includes a general comment letter which refers to two presentations (attached) which were due to be delivered at the cancelled public meeting. We will follow up this Email with a hard copy submission via next day courier.

Thank you for making our response part of the record. If you have any questions please contact me at (813) 960-2105.

Sincerely,

Robert P. Best President/CEO

labert P. Best

RPB/dwm

Attachments



6 July 2004

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

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

Dear Sir/Madam:

ISPE welcomes the opportunity to submit comments in response to FDA questions concerning Part 11. ISPE is an international society promoting the integration of industry professionals and regulatory agencies worldwide to improve the Life Sciences.

The ISPE technical sub-committee known as GAMP Forum has prepared the comments submitted here. GAMP Forum is an international organization with active regional steering committees for USA, Europe, and Japan. Membership includes pharmaceutical companies, suppliers, and consultants. The GAMP Forum is responsible for the GAMP4 Guide and is currently working on new Electronic Record/Signature Guidance.

ISPE/GAMP appreciate the difficulty the Agency has in being completely definitive in this area but believe that the following comments will make the Rule more effective. In particular we believe the proposed changes will help facilitate new technology and innovation (e.g. PAT). Although our comments are largely based on a pharmaceutical sector we believe the points made here are equally applicable to the other sectors subject to Part 11.

- 1) We suggest the Part 11 Rule should be aligned with FDA's Part 11 Final Guidance on Scope and Application issued August 2003. In particular, we encourage the Agency to:
 - Preserve and clarify narrow scope
 - Focus on signatures and records, not data and systems
 - Emphasize role of predicate rules
- 2) The Rule should allow the application and rigor of <u>all controls</u> (not just audit trail, validation, and record retention) to be based on impact and risk. It should be a decision of the regulated organization whether or not they wish to apply a risk-based approach. If a risk-based approach is applied then it should be defined and documented by the regulated organization.
- 3) We suggest that there should be a general expectation that computer systems supporting regulated records and signatures are validated. Not all Predicate Rules clearly identify a requirement for such validation. Any such validation should be commensurate with impact and risk.

3109 W. Dr. Martin Luther King, Jr. Blvd., Suite 250 • Tampa, FL 33607 USA Tel: 813/960-2105 • Fax: 813/264-2816 • www.ispe.org

- 4) Part 11 should concentrate on the <u>principles of what</u> is needed and avoid being prescriptive on the <u>practicalities of how</u> to fulfill Part 11 Rule. For instance, for electronic signatures there should be controls in place to ensure that only the actual (verified) owner of the electronic signature could perform actions recorded against that electronic signature. We suggest that 11.200(a) (3) is replaced with "Electronic signatures must be administered to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner is appropriately controlled."
- 5) We would like to suggest that the preamble to any Part 11 revision is kept as short as possible. If further interpretation is necessary, it should be published as separate guidance and not as part of the preamble. This will allow the Rule to be less prescriptive and, therefore, give it a 'longer life'. It would be very useful if any such additional guidance is released in conjunction with publication of the revised Rule.
- 6) The current Part 11 Rule should be maintained with the accompanying Part 11 Final Guidance on Scope and Application until any revision to the Rule is issued. We believe rescinding Part 11 without replacement would lead to a period of ambiguity until the Agency published their revised requirements.

In addition to these comments, please find attached the two presentations for your consideration that ISPE/GAMP was to have made at the Agency's planned Public Meeting on Part 11 Rulemaking originally planned for 11 June 2004, but cancelled because of President Regan's funeral.

Thank you for the opportunity to comment.

lobert P. Best

Yours Sincerely,

Bob Best

Attachment #1: GAMP Forum Part 11 Comments

Attachment #2: New ISPE/GAMP Guidance on Compliant Electronic Records and Signatures