

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 2003D-0060]

### Guidance for Industry on “Part 11, Electronic Records; Electronic Signatures—Scope and Application;” Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Part 11, Electronic Records; Electronic Signatures—Scope and Application.” The guidance explains FDA’s current thinking regarding the requirements and application of part 11 (21 CFR part 11). FDA has begun to re-examine part 11 as it applies to all FDA regulated products. This guidance explains that we will narrowly interpret the scope of part 11. While the re-examination of part 11 is under way, we intend to exercise enforcement discretion with respect to certain part 11 requirements. With respect to systems that were operational before August 20, 1997, the effective date of the final rule establishing part 11, we intend to exercise enforcement discretion with respect to all part 11 requirements under certain circumstances.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Joseph C. Famulare, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-8940, or [part11@cder.fda.gov](mailto:part11@cder.fda.gov); or David Doleski, Center for Biologics Evaluation and Research (HFM-676), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3031, [doleski@cber.fda.gov](mailto:doleski@cber.fda.gov); or John Murray, Center for Devices and Radiological Health (HFZ-340), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-4659, [jfm@cdrh.fda.gov](mailto:jfm@cdrh.fda.gov); or Vernon D. Toelle, Center for Veterinary Medicine (HFV-234), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0312, [vtoelle@cvm.fda.gov](mailto:vtoelle@cvm.fda.gov); or JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3116, [jziyad@cfsan.fda.gov](mailto:jziyad@cfsan.fda.gov); or Scott MacIntire, Office of Regulatory Affairs (HFC-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-1706, 301-827-0386, [smacinti@ora.fda.gov](mailto:smacinti@ora.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Part 11, Electronic Records; Electronic Signatures—Scope and Application.”

The guidance explains FDA's current thinking regarding the requirements and application of part 11.

In March 1997, FDA issued final part 11 regulations that provided criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records, and handwritten signatures executed on paper (62 FR 13430, March 20, 1997). These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology, consistent with FDA's responsibility to protect the public health.

After part 11 became effective in August 1997, significant discussions ensued among industry, contractors, and the agency concerning the scope, interpretation, and implementation of the regulations. Concerns have been raised that some interpretations of the part 11 requirements would have the following effects: (1) Unnecessarily restrict the use of electronic technology in a manner that is inconsistent with FDA's stated intent in issuing the rule, (2) significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted, and (3) discourage innovation and technological advances without providing a significant public health benefit. These concerns have been raised particularly in the areas of part 11 requirements for validation, audit trails, record retention, record copying, and legacy systems.

As an outgrowth of its current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics, FDA has begun to re-examine part 11 as it applies to all FDA regulated products. We may revise provisions of part 11 as a result of that examination. This guidance explains

that we will narrowly interpret the scope of part 11. While the re-examination of part 11 is under way, we intend to exercise enforcement discretion with respect to certain part 11 requirements. However, with respect to legacy systems we intend to exercise enforcement discretion with respect to all part 11 requirements under certain circumstances. As announced on February 25, 2003, in the **Federal Register** document announcing the availability of the draft version of this guidance (68 FR 8775), we have withdrawn Compliance Policy Guide 7153.17 and previously published part 11 draft guidance documents on validation, glossary of terms, time stamps, and maintenance of electronic records. Also, in the **Federal Register** of February 4, 2003 (68 FR 5645), we announced the withdrawal of the previously published part 11 draft guidance on electronic copies of electronic records.

FDA received a number of comments when it issued the February 2003 draft version of this guidance. We have considered the comments on the draft carefully and have made some changes to address those comments. Among other things, we have revised the guidance by making the following changes:

1. Emphasize that part 11 remains in effect and that enforcement discretion applies only to certain requirements or circumstances as identified in the guidance;
2. Clarify the term ‘enforcement discretion’;
3. Explain that time stamps should be clearly referenced;
4. Remove the National Institute of Standards and Technology risk management guide as a reference and add the ISO 14971 risk management guide as a reference;
5. State that the FDA currently has no plans to re-issue the withdrawn part 11 draft guidance documents; and

6. Clarify the meaning of ‘part 11 legacy system.’

This guidance provides recommendations to persons who, in fulfillment of a requirement in a statute or another part of FDA’s regulations to maintain records or submit information to FDA, have chosen to maintain the records or submit designated information electronically and, as a result, have become subject to part 11.

This guidance announces that we intend to exercise enforcement discretion with respect to the validation, audit trail, record retention, and record copying requirements of part 11. We also intend to exercise enforcement discretion and do not intend to recommend or take enforcement action to enforce any part 11 requirements with regard to systems that were operational before August 20, 1997, the effective date of part 11 (commonly known as existing or legacy systems) while we are re-examining part 11. However, records must still be maintained or submitted in accordance with the underlying predicate rules.

It is important to note that FDA’s exercise of enforcement discretion as described in this guidance is limited to specified part 11 requirements (setting aside legacy systems, as to which the extent of enforcement discretion, under certain circumstances, will be more broad). We intend to enforce all other provisions of part 11 including, but not limited to, certain controls for closed systems in § 11.10, the corresponding controls for open systems (§ 11.30), and requirements related to electronic signatures (e.g., §§ 11.50, 11.70, 11.100, 11.200, and 11.300). We expect continued compliance with these provisions, and we will continue to enforce them. Where the interpretation of part 11 in this guidance differs from the interpretation in the preamble to part 11, the interpretation in this guidance will apply.

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on “Part 11, Electronic Records; Electronic Signatures—Scope and Application.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 27, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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