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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 11**

[Docket No. 00N-0358]

**Technical Implementation of Electronic Records and Electronic Signatures; Public Meeting and Request for Presentation Abstracts**

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

**ACTION:** Notification of a meeting.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on industry's experience in implementing the technical provisions of regulations on electronic records and electronic signatures, and requesting abstracts of presentations persons would like to give at the meeting. FDA and the Parenteral Drug Association (PDA) are co-sponsoring this event. However, participation is not limited to the pharmaceutical industry; all interested persons, from all FDA regulated industries, are invited to participate. The purpose of the meeting is to exchange information on the range of experiences persons subject to these regulations have had in implementing the rule's technical provisions and available products and services that enable implementation of those requirements. This will neither be a forum to discuss the merits of the rule, nor a tutorial on the regulation; meeting attendees should have a basic understanding of these regulations. Information presented at the event will assist FDA in developing future industry guidance documents with respect to these regulations.

**DATES:** The meeting is scheduled for Monday and Tuesday, June 19 and 20, 2000, from 8:30 a.m. to 5 p.m. Abstracts of proposed presentations must be received by March 19, 2000. Handouts

and related presentation materials for accepted abstracts must be received by May 19, 2000. Submit written comments by May 19, 2000.

**ADDRESSES:** The meeting will be held at the Wyndham Franklin Plaza Hotel, 17th and Race Sts., Philadelphia, PA 19103.

Send meeting registration requests, abstracts of proposed presentations and materials for accepted abstracts to the Angie Fischer, PDA, 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814. Material may be sent by electronic mail to PDA at [fischer@pda.org](mailto:fischer@pda.org).

You may view documents related to this event at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

For general information: Steven M. Solomon, Office of Enforcement, Office of Regulatory Affairs (HFC-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0386, FAX: 301-827-0343, e-mail: [ssolomon@ora.fda.gov](mailto:ssolomon@ora.fda.gov).

For information about registration for the public meeting: Angie Fischer, Program Director, PDA, 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814, 301-986-0293 x129; FAX 301-986-0296; e-mail: [fischer@pda.org](mailto:fischer@pda.org).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA (we) issued a final rulemaking for part 11 (21 CFR part 11), electronic records and electronic signatures. The rule went into effect on August 20, 1997. Part 11 is intended to create criteria for electronic recordkeeping technologies while preserving the agency's ability to protect and promote the public health (e.g., by facilitating timely review and approval of safe and effective new medical products, conducting efficient audits of required records, and when necessary pursuing regulatory actions). Part 11 applies to all FDA program areas, but does not mandate electronic recordkeeping. Part

11 describes the technical and procedural requirements that must be met if a person chooses to maintain records electronically and use electronic signatures. Part 11 applies to those records and signatures required by FDA predicate rules, as well as signatures that are not required, but appear in required records.

Part 11 was developed in concert with industry over a period of 6 years. Virtually all of the rule's requirements had been suggested by industry comments to a July 21, 1992, advance notice of proposed rulemaking (57 FR 32185). In response to comments to an August 31, 1994, proposed rule (59 FR 45160), the agency refined and reduced many of the proposed requirements in order to minimize the burden of compliance. The final rule's provisions are consistent with an emerging body of Federal and State law as well as commercial standards and practices.

## **II. Scope of Meeting**

The scope of the meeting will be limited to implementation of part 11's technical requirements. This forum will focus on how persons subject to the rule are finding and using available enabling technologies. We are mindful of the rapid pace at which such technologies are changing and emerging, and the importance of keeping up with products and services that help ensure that electronic records remain trustworthy, reliable, and compatible with FDA's public health protection responsibilities.

Part 11 affords persons substantial flexibility in selecting enabling technologies that meet their respective needs, yet facilitate compliance with the rule. However, the agency is aware that some persons have found it challenging to keep up with available technologies and adapt them to older electronic recordkeeping systems. We expect this conference to help those persons and provide the agency with additional information we will use to develop future part 11 guidance documents.

We emphasize that this meeting is open to all FDA regulated industries (foods, cosmetics, pharmaceuticals, biologics, veterinary, and medical devices) as well as suppliers of computer technologies and services designed for use with electronic records. Attendees will have opportunity to ask questions of presenters.

We encourage all interested professional and trade groups to support this event by advising their members about it and encouraging their participation. Such groups should contact the PDA regarding any additional assistance they would like to provide.

We invite interested persons to give brief presentations about their experiences in implementing one or more of part 11's technical provisions. Likewise, we invite persons who provide enabling technologies specific to those requirements to give presentations addressing how they have been and can be applied to FDA regulated industries. In all cases, presentations must not exceed 20 minutes. Of particular interest would be presentations regarding modifications to electronic recordkeeping systems that were in use before August 20, 1997, (so called legacy systems). Here are some examples of relevant topics:

*Electronic Records Creation:* Methods of ensuring proper sequencing of electronic record entries and construction, use of technology to ensure validity of data input and operational instructions, and transaction controls to ensure that records are generated from the right data sources.

*Electronic Record Integrity and Reliability:* Use of secure electronic audit trails that independently provide transaction date and time stamping of operator entries and actions that create, modify or delete electronic records; use of encryption and digital signatures in support of electronic record integrity and authenticity.

*Electronic Signatures:* Use of biometric and digital signature technologies; linking electronic signatures to electronic records.

*Archiving Electronic Records:* Methods of preserving electronic records, including content, structure, context, audit trail and other security attributes; migration from one file format and computing platform to another; ensuring accessibility by end users and FDA, especially when archiving to an environment different from the one in which the records were initially created.

### **III. Requests to Make Presentations, and Registration**

If you would like to make a presentation at this meeting, send a brief abstract (no longer than one page), along with the speaker's name, affiliation, title, postal address, fax and phone numbers, and electronic mail address to PDA (address above).

If you elect to send your abstract and speaker information by electronic mail, send the material in Adobe(r) PDF (portable document format), or ASCII (American Standard Code for Information Interchange) format to [fischer@pda.org](mailto:fischer@pda.org).

Abstracts of proposed presentations, along with speaker information, must be received by March 19, 2000. FDA and PDA will jointly determine which abstracts to accept, and authors will be notified. Presentation handouts and related materials for accepted abstracts must be received by May 19, 2000. (Speakers who miss this deadline but wish to give meeting attendees copies of their material should bring sufficient copies with them at the time of the meeting.)

To register for the meeting, contact the PDA at the address above. Also, see the association's Internet site at <http://www.pda.org>. If you need special accommodations due to disability, please inform the PDA contact person above when you register.

### **IV. Public Docket**

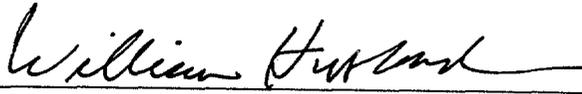
You may review the documents related to this meeting in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday. These documents include the co-sponsorship agreement between FDA and PDA for this event, presentation abstracts and speaker information materials, and presentation handouts upon completion of the meeting.

### **V. Comments**

Interested persons, including those unable to attend or speak at the meeting, may send us comments regarding their experiences in implementing part 11's technical provisions, and their products or services that help people meet those requirements. Send paper comments

on or before May 19, 2000, to the Dockets Management Branch (address above). You may also send comments electronically to the Dockets Management Branch via the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 14, 2000



William K. Hubbard  
Senior Associate Commissioner  
for Policy, Planning, and Legislation

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