dated October 30, 1997, including Addendum; or Boeing Service Bulletin 747–53A2410, Revision 3, dated March 12, 1998, including Addendum. After the effective date of this AD, only Revision 3 shall be used.

(1) For airplanes that have accumulated fewer than 17,000 total flight cycles or 63,000 total flight hours as of the effective date of this AD: Inspect at the later of the times specified in paragraph (a)(1)(i) or (a)(1)(ii) of this AD.

(i) Prior to the accumulation of 17,000 total flight cycles or 63,000 total flight hours, whichever occurs first.

(ii) Within 1,800 flight cycles or 7,000 flight hours after the effective date of this AD, whichever occurs first.

(2) For airplanes that have accumulated 17,000 total flight cycles or more, or 63,000 total flight hours or more, as of the effective date of this AD: Inspect at the earlier of the times specified in paragraphs (a)(2)(i) and (a)(2)(ii) of this AD.

(i) Prior to the accumulation of 22,000 total flight cycles or 78,000 total flight hours, whichever occurs first.

(ii) Within 1,800 flight cycles or 7,000 flight hours after the effective date of this AD, whichever occurs first.

Note 2: Where there are differences between the AD and the service bulletin, the AD prevails.

Note 3: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Repetitive Inspections

(b) If no crack is found during the inspection required by paragraph (a) of this AD, repeat the inspection one time at the later of the times specified in paragraphs (b)(1) and (b)(2) of this AD, and thereafter at intervals not to exceed 3,000 flight cycles or 18,000 flight hours, whichever occurs first.

(1) Within 3,000 flight cycles or 18,000 flight hours after accomplishment of the most recent inspection, whichever occurs first.

(2) Within 1,800 flight cycles or 7,000 flight hours after the effective date of this AD, whichever occurs first.

Replacement and Repetitive Inspections

(c) If any crack is found during any inspection required by paragraph (a) or (b) of this AD: Prior to further flight, replace the cracked fitting with a new fitting, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2410, Revision 2, dated October 30, 1997, including Addendum; or Boeing Service Bulletin 747–53A2410, Revision 3, dated March 12, 1998, including Addendum. After the effective date of this AD, only Revision 3 shall be used. Then, repeat the inspection specified in paragraph (a) of this AD at the later of the times specified in paragraphs (c)(1) and (c)(2) of this AD, and thereafter at intervals not to exceed 3,000 flight cycles or 18,000 flight hours, whichever occurs first.

(1) Within 17,000 flight cycles or 63,000 flight hours after replacement, whichever occurs first.

(2) Within 1,800 flight cycles or 7,000 flight hours after the effective date of this AD, whichever occurs first.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on February 15, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–4121 Filed 2–18–00; 8:45 am]

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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.

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.

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.

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.

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.

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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