VII. When Do I Submit the Fee for Applications Submitted On or After the Date of Publication of This Notice?

A. Payment Options for Firms Submitting Medical Device Applications between Today and March 31, 2003.

If you submit a medical device application subject to fees on or after the date of publication of this notice, and before April 1, 2003, you may either:

(1) Submit the application without first submitting payment, and pay the fee when an invoice is received; or

(2) Pay the fee at the time the application is submitted.

B. Payment Requirement for Firms Submitting Medical Device Applications On or After April 1, 2003.

If you submit a medical device application subject to fees on or after April 1, 2003, you must pay the fee for the application at or before the time the application is submitted. If you have not paid all fees owed, FDA will consider the application incomplete and will not accept it for filing (21 U.S.C. 379j(f)).

VIII. What Are the Procedures for Paying Application Fees?

FDA requests that you adhere to the following steps before submitting a medical device application subject to a fee. Please pay close attention to these procedures to ensure that FDA associates the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)

A. Step One—Secure a Payment Identification Number and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment.

Log onto the MDUFMA Web site at http://www.fda.gov/oc/mdufma, and under the ''Forms'' heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee Cover Sheet and print a copy. Note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

B. Step Two—Fax a Copy of the Printed Cover Sheet With the Payment Identification Number to FDA's Office of Financial Management.

The FDA facsimile machine phone number to receive this completed Medical Device User Fee Cover Sheet is 301–827–9213. FDA will then enter the information into its accounting system, in order to associate payments with submitters. (Note: Later this year, after the Web site is upgraded, you will be able to transmit the completed form electronically and you will not need to fax a copy to FDA.)

C. Step Three—Mail a Copy of the Completed Medical Device User Fee Cover Sheet and the Payment for Your Application to the St. Louis Address Specified in Item 3 as Follows:

1. Make the payment in U.S. currency by check, bank draft, or U.S. postal money order payable to FDA. (The tax identification number of FDA is 53–0196965, should your accounting department need this information.)

2. Please note on your payment your application's unique Payment Identification Number from the upper right-hand corner of your printed Medical Device User Fee Cover Sheet.

3. Mail the payment and a copy of the completed Medical Device User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733.

If you prefer to send a check by a courier, the courier may deliver the checks to: US Bank, Attn: Government Lockbox, SL–MOC1GL, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records as the application receipt date the latter of the following:

a. The date the application was received by FDA; or

b. The date US Bank notifies FDA that payment has been received. US Bank is required to notify FDA within 1-working day, using the Payment Identification Number described in section VIII, C.2 of this document.

D. Step Four—Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet.

Please submit your application and a copy of the completed Medical Device User Fee Cover Sheet to one of the following addresses.

1. Medical device applications should be submitted to: Document Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

2. Biologic applications should be sent to: Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1428.

Dated: February 13, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–4490 Filed 2–21–03; 11:22 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 03D–0060, 99D–1458, 00D–1538, 00D–1543, 00D–1542, and 00D–1539]

Draft Guidance for Industry on ''Part 11, Electronic Records, Electronic Signatures—Scope and Application;'' Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application.'' This draft guidance explains FDA's current thinking regarding the requirements and application of part 11 (21 CFR part 11). As an outgrowth of its current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics, FDA is embarking on a re-examination of part 11 as it applies to all FDA regulated products. We may revise provisions of part 11 as a result of that reexamination. The draft guidance explains that while this re-examination is under way, we intend to exercise enforcement discretion with respect to certain part 11 requirements. We are also announcing the withdrawal of Compliance Policy Guide (CPG) 7153.17 and previously published part 11 draft guidance documents on validation, glossary of terms, time stamps, and maintenance of electronic records.

DATES: Submit written or electronic comments on the draft guidance by April 28, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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, or to the Division of Compliance Policy (HFC–230), Office

of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph C. Famulare, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8940, 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; 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; 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; 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; 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.

SUPPLEMENTARY INFORMATION:

I. Background

In March 1997, FDA issued final regulations (part 11) 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.

Since part 11 became effective in August 1997, significant discussions have ensued between industry, contractors, and the agency concerning the interpretation and implementation of the rule. Concerns have been raised that some interpretations of the part 11 requirements would: (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.

This document provides guidance 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 draft 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. However, records must still be maintained or submitted in accordance with the underlying predicate rules. We also intend to exercise enforcement discretion and will not normally take regulatory action to enforce part 11 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 reexamining part 11.

It is important to note that FDA's exercise of enforcement discretion as described in this guidance is limited to the specified part 11 requirements. 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.

In the **Federal Register** of February 4, 2003 (68 FR 5645), we announced the withdrawal of the draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records'' because we wished to limit the time spent by industry reviewing and commenting on the guidance, which might not have been representative of FDA's approach under the CGMP initiative.

At this time, we are also announcing the withdrawal of CPG 7153.17 and previously published part 11 draft guidance documents on validation, glossary of terms, time stamps, and maintenance of electronic records. FDA has determined that it might cause confusion to leave standing these other draft guidances on part 11 and CPG 7153.17. FDA received valuable public comment on the draft guidances and plans to use that information to inform the agency's future decisionmaking with respect to part 11.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, 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 draft 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 draft guidance at *http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/ora under ''Compliance References,'' or http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: February 19, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–4312 Filed 2–20–03; 8:45 am]

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