

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.

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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