Dear Colleague:

The Food and Drug Administration (FDA) has enhanced the Medical Device Application Cover Sheet website to improve the tracking of your organization's application payments. With these improvements to the MDUFMA coversheet, we will be able to improve service, one of MDUFMA's performance goals.[1] The new system will be available on **March 1, 2005**. FDA plans similar improvements for all of its user fee programs.

The Website continues to allow you to electronically obtain your user fee payment identification number and to submit your Medical Device User Fee (MDUFMA) cover sheets (FDA Form 3601).

To register, please follow the following steps:

1. Navigate to the following page: www.fda.gov/oc/mdufma/coversheet.html.
2. Click on the 'Create a Medical Device User Fee Cover Sheet' link.
3. On the next page, click on the 'New User, Please Register' link to begin the registration process. You will need one of the following pieces of information to complete the registration process.

Organization # [2]	12345
Dun & Bradstreet # (DUNS)	123456789
Employer Identification # (EIN)	123456789

   Please note that even if you have registered in the MDUFMA User Fee cover sheet system previously to March 1, 2005, you will need to follow the instructions noted above and consider yourself as a "New User".

4. When you have completed the registration process you will receive a confirmation via email. If you choose you may continue to create a Medical Device application cover sheet. After you have entered your application information, the system will automatically generate a user fee payment identification number.

Additionally, we will need you to identify a Principal Point of Contact (PPOC) in your organization who will be responsible for validating users for security purposes. Please email your designated PPOC's contact information including name, phone number, street address, and email address to userfees@fda.gov.

Thank you in advance for your continued cooperation and for contributing to the success of this program. Please feel free to contact the OFM User Fee Team at userfees@fda.gov or (301) 827-9539, should you have any questions.

Sincerely,

ROBERT M. NAVAZIO
Assistant Director for Strategic Planning
Center for Devices and Radiological Health

[1] This Web-based user fee system has been successfully implemented for animal drug products under the Animal Drug User Fee Act (ADUFA) in FDA. If your organization produces animal drug products, you may be familiar with the system. However, even if you are registered under the ADUFA system, you will have to register as a "New User" under the MDUFMA system.

[2] The Organization Number is an FDA-generated number used to uniquely identify each organization. If your organization has already registered under the FDA's ADUFA system, you already have an organization number.