



August 2008

### Highlights:

- A New Way of Processing
- Take Note
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- Pay, Then Register

## 2009 Device Facility Annual Registration

October 1, 2008

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December 31, 2008

## Questions?

Email us at: [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov)

### Food & Drug Administration

#### A New Way of Processing

On October 1, 2008, FDA will introduce an improved process for collecting device facility (also known as “establishment”) user fees and registrations. As a result, the process you used last year to submit your device facility user fee and registration will change. You are receiving this letter to prepare you for this process change. This letter indicates the actions you need to take to make sure you complete the process correctly.



The process changes do not impact the facilities that are not required to pay the user fee. However, the process changes do impact the facilities that are required to pay the device facilities user fee.

#### Take Note



The most significant change in the process will be that you must pay your user fee before you register your facility. In other words, **you cannot register until you pay your user fee** (if applicable). If both the payment and registration are not submitted correctly and completely, the facility registration remains incomplete. Make sure you leave enough time for FDA to process both your payment and confirm your registration before December 31, 2008, especially if you are mailing a check.

#### Who?

You must pay the facility user fee if you are a:

- U.S. or foreign based manufacturer of devices that are commercially distributed in the U.S.
- U.S. manufacturer of devices produced for export out of the U.S. only
- U.S. contract manufacturer who commercially distributes the device for the specifications developer
- U.S. contract sterilizer who commercially distributes the device
- Foreign contract manufacturer or sterilizer whose device is shipped to the U.S. either by the contract manufacturer or by any other foreign establishment
- Reprocessor of single-use devices commercially distributed in the U.S.
- Developer of specifications for a device that is manufactured by another party
- Kit Assembler

For more information on who must pay the fee, please visit:  
<http://www.fda.gov/cdrh/registration/whomust.html>



Firms must complete **both** their payment and registration between October 1, 2008 and December 31, 2008.

Turn Over

## Pay, Then Register

If your facility is *not* required to pay the user fee, proceed to step #3. Otherwise, begin at step #1. If you are unsure whether or not you need to pay the user fee, please return to the front page of this letter and review the **Who?** section.

**1****Sign up**

Go to the Facility User Fee website: [https://fdasfinapp8.fda.gov/OA\\_HTML/furls.jsp](https://fdasfinapp8.fda.gov/OA_HTML/furls.jsp)  
Once at this website, create an account to enter the website. Domestic firms must enter their taxpayer ID. You do not need to create an account if you signed up with another FDA user fee website in the past; in this case, use that same account information to log onto this website. (Note: Your ID and password for the Facility User Fee website is different than your FURLS ID and password.)

Log onto the website with the username and password you just created and enter the quantity of user fees for which you need to pay. The screen displays a Payment Identification Number (**PIN**). Your **PIN** is exactly as its name implies: it is a number that identifies your payment. However, please note that although you receive your **PIN** at this stage, you have not completed your payment yet. **You will need your PIN to register your facility.** Record the **PIN** in the space provided below.

**2****Pay**

Complete your payment online by entering your credit card or electronic check information. You may also complete your payment by mailing in a check. Your check must be issued by a U.S. bank. After FDA processes your payment, you will receive an email with a unique Payment Confirmation Number (**PCN**) for each facility for which you paid a user fee. *One PCN* confirms a payment for *one* facility. **You will need your PCN(s) to register your facility.** Record your **PCN(s)** in the space provided below.

**PIN****PCN****Record your PIN and PCN:**

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**3****Register**

Log onto FURLS at <https://www.access.fda.gov/oa/> with the ID and password you used for your 2008 registration. **Do not create a new ID and password if you do not remember yours.** You will receive a future mailing with your user ID and instructions on how to retrieve your password. If you did not pay a user fee (because you are not required to pay), then proceed to review your annual registration or enter your new registration info.

If you did pay a user fee and have received your **PIN** and **PCN**, review/enter your registration information once logged onto FURLS. The system will prompt you to enter your **PIN** and **PCN**. You must enter this information for FDA to accept your registration; **without your PIN and PCN, your registration is incomplete and you will have to enter your information again.** Go to step #1 of this page if you do not have a **PIN** and **PCN** but the system asks for them. In this case, you owe a user fee payment and must complete the above steps (steps 1 and 2) before registering.