Registration and Listing

When you log in to the Electronic Registration and Listing System (FURLS), you may be required to reset your password. This is a security feature and will happen every 90 days.

Emails confirming the current status of each firm's 2008 registration are being sent out. Due to the volume of mail that has resulted from these emails, it may take up to 10 business days for you to receive a response to your inquiry. Please DO NOT resend your email or phone us. Emails will be responded to in the order that they are received.

Information about which establishments have to Register, List and Pay the Registration Fee can be found here.

Note: If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System (FURLS), please send an email to reglist@cdrh.fda.gov. If you have already received your account ID and password letter and your password is less then 8 characters, you will not be able to access the system. Please contact the registration desk by Email at reglist@cdrh.fda.gov for assistance.

Owners or operators of places of business (establishments) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration. There is a fee for annual establishment registration for some establishment types.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).

The amendments to the Medical Device User Fee Modernization Act require that after September 30th, 2007, all registration and listing information be submitted electronically, unless a waiver has been granted.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

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