



Cost Effective Compliance with FDA's New Electronic Registration Process

Beginning June 1, 2009, the FDA eliminated its traditional paper-based registration process for drug manufacturers, including all medical gas manufacturers. Instead, FDA now requires facility registration information be submitted electronically -- in a special process, called Structured Product Listing (SPL), using electronic forms.

Completing FDA's new process is both time consuming and full of specific and highly detailed requirements. Additionally, FDA now requires additional information it has never historically asked for. The new reporting process is very complicated, and involves submitting three separate electronic forms in a specific order. But, before submitting the forms to FDA, every company must first establish its own secure electronic gateway into the agency.

Once you've seen these requirements, you'll quickly realize that avoiding all the pitfalls and successfully navigating through this new process, requires some very specialized training and experience.

Relief is Now at Hand

Reg-E-Stration, a company formed just to meet this new registration challenge, and now provides a turnkey service for pharmaceutical and medical gas manufacturing firms to transition into this new registration process. We simplify the process, because we have the expertise and experience to make this a quick and painless procedure. Reg-E-Stration makes things easy, because all you have to do is provide us with some basic information about your company and we do the rest.

The Reg-E-Stration Turnkey Solution for FDA Registration

Facility Registration

We complete your SPL facility registration on FDA's electronic form, and document each of your sites with all the required information, including the DUNS number FDA now requires.

NDC Labeler Code Request

We complete your SPL NDC Labeler Code application on FDA's electronic form for each of your drug products, making certain all the required information is included, especially all of your individual package sizes for each product

Drug Listing

We complete the SPL Drug Listing on FDA's electronic form for every drug label in your inventory. In addition to adding the required information, we also code each label into the xHTML format and also embed a scanned image of the label into the form as required by FDA.

Web Portal Setup and Document Submission

We establish a secure web portal for you into FDA, and obtain the required computer security certificates. We submit the SPL forms for you through the gateway in the proper order. Most importantly, we assure your registration forms are correctly received and filed with FDA.

Annual Re-registration, Updates, & Web Portal Maintenance

Annually, Reg-e-Stration will re-submit your registration and file any changes to your information with FDA.



Pricing

Our fees are based on the size and complexity of your organization and manufacturing operations. We charge a very reasonable one-time fee for services in the first year to convert and submit your electronic files and set up your secure web portal. Once you are registered through Reg-E-Stration, we charge a minimal annual fee to cover the maintenance of your registration and secure web portal, and annual re-registration of your business. For more information or a price quote to for your business, please give us a call at (610) 390-7483.

About Reg-E-Stration LLC

Reg-E-Stration is a joint venture company between B&R Compliance Associates LLC, a leading regulatory and compliance consulting company in the medical gases industry, and Quality Partners LLC, a provider of compliance solutions in the medical device and pharmaceutical industries. The combined experience of both companies encompasses virtually every aspect of developing and implementing cost effective FDA compliance solutions. We have the background, training, and experience to solve any FDA registration issue you might have.

Contact Us

For more information on our services, or to get a price quote on registering your company with FDA through Reg-E-Stration give us a call at (610) 390-7483, or visit us online at www.reg-e-stration.com.