

FDA Electronic Registration/Listing Update (9 Dec 2009)

Your GAWDA and CGA medical gas representatives met with the FDA on Friday, December 4, 2009. The FDA was firm in the requirement to conduct the electronic registration. However, the FDA shared with us their interpretation of "Annual Renewal." This definition is somewhat different from what we had assumed.

"Annual Renewal" means anytime in the calendar year before 12/31 of that year. Therefore, the FDA considers your renewal to be current if you register before the end of the year (12/31/09 for 2009; 12/31/2010 for 2010). This has important implications for most of the GAWDA members who registered via paper in the first half of 2009.

Executive Summary - If you registered by paper in early 2009, there is no rush to register electronically. In most cases, you are registered until 12/31/2010. See details below.

The Full Details

The following sections will discuss drug registration from the following points of view:

- The FDA Regulations
- The Food Drug and Cosmetic Act (The Law)
- FDA's use of "Enforcement Discretion" and "Guidance"
- Unusual Drug Registration Issues.

The FDA Regulations

The actual FDA regulation regarding annual registration is: 21 CFR 207.21 Times for registration and drug listing. (a) The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a list of every drug in commercial distribution at that time. Owners or operators shall renew their registration information annually.

The schedule is as follows:

First letter of company name	Date FDA will mail forms
A or B.....	January
C, D, or E.....	February
F, G, or H.....	March
I, J, K, L, or M.....	April
N, O, P, Q, or R.....	May
S or T.....	June
U, V, W, X, Y, or Z.....	July

There are a few problems with this regulation:

1. Contrary to their own regulations, the FDA no longer mails the registration forms.
2. The next section, 207.22, specifies that the FDA will send us a Form 2656. They no longer use the Form 2656 to register.

The Food, Drug and Cosmetic Act

In the Food, Drug and Cosmetic Act, we find the actual basis for “Annual Registration”:

SEC. 510. [21 USC §360] Registration of Producers of Drugs and Devices
1(b) Annual registration.

1) On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary his name, places of business, and all such establishments.

This is the basis for the “calendar year” definition of the word “annual.”

FDA’s use of “Enforcement Discretion” and “Guidance”

Even the FDA acknowledges that their regulations are not up to date with their actual compliance practices. The FDA uses the term “Enforcement Discretion” to allow them the flexibility to enforce the regulations according to their needs. In other areas, “Enforcement Discretion” benefits the medical gas industry since several FDA regulations are simply not appropriate for medical gases.

In May, 2009, the FDA published “Guidance for Industry - Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing.” This document, along with *Federal Register* postings, gives the FDA the authority to enforce the registration and listing requirements differently from their own regulations. The guidance states, “Owners or operators must renew their registration information annually (Section 510(b)(1) of the Act; 21 CFR 207.21(a)).” Since 510(b)(1) of the Act specifies 12/31 of each calendar year to be the registration deadline, the guidance continues the practice of the FDA to require electronic registrations on a calendar year basis.

Unusual Situations

You are required to register within five (5) days of beginning drug manufacturing or a change in business ownership. Under the present electronic registration systems, it is impossible to complete the registrations in a timely manner. The FDA is well aware of this. Contact tom@asteriskllc.com if you need to expedite a registration.

Some states require a current federal registration before they will allow a firm to be licensed to manufacture drugs. We asked the FDA for a clarification of this calendar year definition so we could help educate the states. If/when we get the clarification from the FDA, we will make it available to you and your state board of pharmacy. Contact Tom Badstubner if you are having challenges with getting your firm licensed by the state because of a delay in federal registration.

Current Status

Well over a hundred medical gas companies have now successfully registered with the FDA using the new electronic registration procedures. By far, the largest barrier to registration is the establishment of the communications between your PC and the FDA’s mainframe (firewalls, JAVA Runtime, security settings, etc.)

If you have registered in 2009, you are not usually required to have your 2010 registration completed by the first of the year. This is different from the message others are saying, and we thought it important that you have the full details before making your decision about when to register. AsteRisk encourages you to register at the same time each year, but it is not a federal compliance problem if your registration takes longer, so long as it is complete before the end of the calendar year.