What is the drug manufacturer registration deadline?

The Law
Congress established the law requiring registration. The Federal Food Drug and Cosmetic Act lays the foundation for FDA drug manufacturer registration:

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

The Regulations
The FDA established regulations in accordance with the law above. The regulations for registration are found in 21 CFR 207:

> *§ 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. If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, request for addition to the index, medicated feed mill license application, or a biologics license application. 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

A side note… the FDA does not follow their regulations in this matter since they no longer mail the registration forms at all, and certainly not according to their schedule.

The Guidance
The FDA published guidance in May 2009 to, effectively, rewrite the process for drug manufacturer registrations. This guidance established an electronic registration requirement. Through the guidance claims it "***Contains Nonbinding Recommendations",*** there is no other way to register a drug manufacturer since they no longer accept the paper based Form 2656 as required by 21 CFR 207.

A paragraph on page 4 of the guidance states:

> *Section 510 of the Act and 21 CFR part 207, subject to certain limited exceptions, require establishment owners and operators (registrants) upon first engaging in the manufacture, preparation, propagation, compounding, or processing of drugs, (including human drugs, veterinary drugs, and biological drug products) to register their establishments and submit listing information for all drugs in commercial distribution. Registrants are also required to submit registration information for their establishments on or before December 31 of each year. At the time of registration, registrants must also submit required listing information. Additionally, registrants are required to update listing information in June and December of each year to include information for drugs that have not been previously listed7 Certain changes to information for previously listed drugs must also be submitted every June and December.*

This "calendar year" definition of the annual registration is clarified in this guidance.

The Meeting with the FDA
The FDA invited GAWDA and CGA representatives to a meeting on December 4, 2009 at their headquarters. During the meeting, the deadline for registration was discussed in detail. The compliance office stated clearly that the annual registration is due befre December 31 of each year.

Our recommendation
Even though you are not required to register before December 31, we recommend that you register early in the year. This is simply because your customers, some accreditation bodies and some state officials do not fully understand the issue. You may find yourself explaining the FDA expectations more often than necessary if you register later in the year.

References:

- **Section 501 (b)(1) of the Federal Food Drug and Cosmetic Act:** http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm109201.htm
- **21 CFR 207(a);** http://ecfr.gpoaccess.gov/cgi/t/text/text-

idx?c=ecfr&sid=33bb7fba3b1cdbad820c4832d150beb3&rgn=div8&view=text&node=21:4.0.1.1.7.3.1.2&idno=21

- **Guidance For Industry:** http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf