**REMINDER: FDA Facility Re-registration Deadline Dec. 31**

*Source:  American Feed Industry Association (AFIA)*

Animal food facilities are responsible for re-registration with the Food and Drug Administration by December 31.  This is required in even-numbered years by the Food Safety Modernization Act. Medicated feed mills, where the mill holds an approved medicated feed mill license, must re-register every year. These are two different registrations and each has a separate set of requirements.

**Registration of Animal Food and Ingredient Facilities**

FSMA requires each food, animal food or ingredient facility to renew its registration under the Bioterrorism Act of 2002 between the months of October and December of even-numbered years. With 2016 falling in that category, the deadline for each facility to re-register is Dec. 31.

Food, animal food or ingredient facilities that manufacture, process, pack or hold food, animal food or ingredients, must register each facility as required by the Bioterrorism Act unless the facility is exempt because it is a "farm." Facilities under a common ownership of the feed mill, animals and land are considered "farms" and are exempt from facility registration; meaning those feed mills do not need to register.

On July 14 of this year, FDA published the final rule on "[Amendments to Regulation on Registration of Food Facilities](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGc6nChTPopYhQ1HgePcCI6MY8AYK8gS5FNLioLD9qYrRsYz53iPoCPQ6qUg4QKTntla_Qpinp5vzGNCjv_kcJr-HvstmqcyViv3PcyzwI3nUgRl2yaWsFZo81N53VxN9wh5Q4gF9uc5--d_Vb4J9KpgPwwKgB_YnDlrgIFWSlr6Q2lGZvo17s7iKwLON_QSEOOIL4cH-uywMUgBgpGmlceEqZYOj0FvOmXbgRXFpFuc13-Ky5DXi8l1aFU0AiIq6zQ8A8dY2ySkgQxtk-uxsBxL2qGgqhltdzNZ7aTm5mK50VjXMOzVMh-4aQt2dnlyFly-dsRTXNFRG9JNbvKkMsQG0=&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==)," Title 21 of the Code of Federal Regulations (CFR) Part 1 (21 CFR Part 1), which added a new provision to the registration of food facilities. The final rule requires firms to register electronically with FDA, renew registration every other year and submit additional registration information, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug and Cosmetic Act.

FDA's facility registration webpage can be found [here](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGc9imWVajp-hcuAqR2EPa7cMHaOdiL1736DNiSF78FNRp3XyHxv06d4_C9ICvGSVLvHlk2Uzfn_XltkdjCSW3C8yAY9zQsjSMsVJZ8KX45X8j-_sWOj8zbJi4FH_0GlJYMg0WCX3J6Omfq0kmTrh3siLUaxMz15iJjWs83jnGDCwnay4a-qwlZz0n8NyvxLAaN2U2_7sHm9K6&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==) (click "Login/Create New Account" to begin). If you have misplaced your facility registration information, contact the FDA District Office and provide proof that you are the owner, operator or agent in charge and they can provide this to you. The directory for the FDA District Offices is located [here](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGc6nChTPopYhQfAqVl7JNTpY9ThmeI3_MFruPHR8R7RJ37kqQmz8D6yqdrpQpb1MqEr557sPUPsz3aZwBFo88i71aaVNr0bH3JDzCtaGyB4az9ANH6dGtJSfxE89mL8mIgYHF5vYu9yxfGDR7tIm083fiDhiaPnqGsH8heWyH3mRMaCLFWZdjRKs=&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==).

**FDA Guidance Documents**

[The Guidance for Industry: What You Need to Know About the Registration of Food Facilities - Small Entity Compliance Guide:](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGcy3LSarUSpDHI2S8gOitPknIZHTv0zVdtRZsoAJ4aqX02F2i1pp4R61SCkNDS93hhTdwA-TLvHcsgkhTezN479e8GIuuFMzFGsKeAbpGx8Ta4P4XicCdVv9wteEGVIzukIolvsHby9mCJWlXrmbYn8zSK_etyiwXCUzu3whEmSWNKPWwKabd0puXzwI8538F68jo7icLGsyoDSayf1sl4Yr2_OwyhwMmfw==&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==) Was updated in 2012 to reflect FSMA amendments to the FFDCA, and contains information regarding who is required to register and who may be exempt; how often facilities must register and renew registrations; when FDA may suspend a registration; and how facilities may submit registrations and registration renewals to FDA.

[The Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition):](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGcy3LSarUSpDHVK5JWzKFdDhVXT_EP78-uf1Z-Rk1tm2poEAFb3YEn0dYKXDDX9F7TLXC0Oxjd58AkNb2ElRtbSNKO3LYA_cyU0Fu9_HCXe7yKN2tjVYBeQFY05_3RNHDqzObAhyjHXCKl4LTBiaOxqpYXGi2qAh6BZakPXCnUgIPer6C9IQtEmsx0I3m1vBboETycjyjCF5_uKh37HQ9FhwVwoCfDBv1qA==&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==) Was updated in 2014 and contains helpful questions and answers regarding food facility registration. Updates to questions in this edition are based on FSMA amendments.

[The Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registration:](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGcy3LSarUSpDHcR0j3pwpw-VdovBUoWJ3pRsT-0falgdxlNCwYwwqVok5VILBqECCG1AEkJMHV3I7h4qEXuMo0e6MndiJL9BqMg1Eo7k5nLOaBgiK6e6I9Lmuq4kpCQZKW99m6-N8iNH_9p5rirXxJ5eRLGB4EXt6JA33xdYGNAzaMQYzxbtQj4UnSqCl6CxaMIN8AOMx-R1CDNhYKXDz-vKCTJbJAR2lnQ==&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==) Contains information regarding food-product categories included in the food facility registration form. Today FDA released updated guidance with new food facility registration product categories to select during the registration process. The agency said the guidance "will help enhance FDA's ability to respond quickly and accurately to food-related emergencies."

**Registration of Drug Establishment (DER)**

Medicated feed mills share the same deadline for drug establishment registration but on an annual basis. According to FDA, firms that send its initial or annual registration during the Oct. 1 to Dec. 31 period are considered registered until the end of following year. If a firm submits its initial, updated or annual registration outside this time frame, it is considered registered until the end of the current year and must renew before Dec. 31.

Registration information can be found [here](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGcy3LSarUSpDHdcrQ1lEgA9nmQc_vLQtax3AlrqmHcOyO4fqYzn1zKZkhzDMXwUkhUVVhHH-LgPq-CEXFBbaFdSQxVgNv0WoeE2dtuIeRx-JBGXX_KWQPyOQjlVVWKvk25iU5FMvhZ2f83eXVZuwMvh1YwDElvue2wcMSeCCJdMKMa9grq7_Osp6X77h5m-9Xp69ZmiAMmj-qBF1YE2ktSuebjZg6uwsaOg7Mf4vgrk8E&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==). This is a separate requirement from the food facility registration mentioned above.

Feed mills required to register as a drug establishment are those that hold an approved medicated feed mill license as defined in Title 21 of the Code of Federal Regulations (CFR) Part 515 (21 CFR, Part 515). These are feed mills manufacturing feed from Category II, Type A medicated articles (premixes) or those that manufacture certain liquid feeds and free-choice feeds from Category I Type A medicated articles. Information on registration and medicated feed mills licensing can be found on the [FDA website](http://r20.rs6.net/tn.jsp?f=001Re6t1JML3XbUC15BOZljWRK0c9t5xDZY_Jq887IrTeSWksty34GGc6nChTPopYhQ6qVmEPExmcwGjTQjm00McxFeZTHSGpn0m28SNp-P5CdO9wYs57-IyEVcoswKvYKCJuCbd_FaSxEaQSvR-8YUm2vq9xRUEsekI7d02A8J6Pf94R-3a8kEqYr_WeJkkEoTdlaNcxSX6gQxLpOJbkVcFlT2tUiJ92eJ-lkF2Q3bpwVGWXefexgjH8NPxK0Tt6sV_etZaEQVj28=&c=-4bSCug1tkZkGfBvF4i_i9mxcxm3Iu6OQ4XUhvWhT2np8aWAxOp72g==&ch=YfZ392Si4XTlexECXxYsASUegSOFmLrcgSsqi2E53xA7b-vnc7s7LQ==).

Before a seller can ship an animal drug intended for the use of manufacture of medicated animal feed, s/he must have a written statement from the buyer that states the buyer has an approved feed mill license and possesses a current approved Type B and/or Type C feed labeling for the drug unless exempt by FDA.

**Final Thoughts on Registration**

There is no fee for facility registration/re-registration or fine for not registering for both medicated feed or food facilities, but it is required by law; if you do not re-register by Dec. 31, your food facility registration will expire and be removed from your account. Also, if the facility's ownership, address or contact person/information has changed, FDA must be notified and information must be changed within 60 days by visiting the facility registration website.