

Questions Regarding Whether Food Facilities are Required to Pay Registration Fees and Private Businesses Claiming or Suggesting an Affiliation with FDA

Updated March 2018

The United States Food and Drug Administration (FDA) continues to receive questions from food facilities regarding whether such facilities are required to pay registration fees or use third-party businesses to register with FDA. In response to these questions, FDA clarifies that there is no fee required to register a food facility with FDA and food facility registrants are not required to use a third-party business or “registrar” to register their facilities with FDA. Additionally, FDA is aware that private businesses are offering services (such as U.S. agent listing and registration renewal services) to food facilities. U.S. Agents may charge a fee for their services, which is solely an issue to be decided between the food facility and the person who agrees to serve as the food facility's U.S. Agent. FDA would like to remind registrants that FDA is not affiliated with these private businesses, nor do they act on FDA’s behalf.

1. FSMA amended section 415 of the Federal Food, Drug, and Cosmetics Act (FD&C Act) [21 U.S.C. § 350d], which requires domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. to register with FDA unless an exemption applies (see 21 CFR 1.226). Food facilities that are required to register with FDA must register directly with FDA electronically or by mail or fax. There is no fee to register with FDA (21 C.F.R. 1.231(c)). A food facility may register, update, or cancel its registration itself (or authorize another person to do so on its behalf) using the Internet at <http://www.access.fda.gov>. Alternatively, a food facility may register, update, or cancel a registration by mail by requesting the appropriate form from U.S. FDA at 1-800-216-7331 or 240-247-8804 outside the United States, or by e-mail at furls@fda.gov. FDA issues a registration number to registered food facilities. Any registered food facility may obtain its registration number by contacting FDA. Note: Traders/brokers, in accordance with Section 415 of the Federal Food, Drug, and Cosmetic act, are **not** required to register.
2. Food facilities do not need a certificate of registration. FDA does not issue a certificate of registration or product status (e.g., low acid canned food), nor does FDA recognize a certificate of registration or product status issued by a private business. If such a certificate of registration is issued by a private business, FDA reminds issuers that the FDA logo is for the official use of FDA and not for use on private sector materials. To the public, such use would send a message that FDA favors or endorses a private sector organization or the organization’s activities, products, services, and/or personnel (either overtly or tacitly), which FDA does not and cannot do. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability. For more information of the use of the FDA logo, please see the complete policy at <https://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ucm218116.htm>
3. Food facilities that have registered and do not have their FURLS information or PIN should not re-register. Instead, a food facility can contact FDA for help at 1-800-216-7331 or 240-247-8804, or by e-mail at furls@fda.gov.

A food facility will be asked to provide information on its company's letterhead signed by the owner, operator, or agent-in-charge of the facility to verify the information. Once FDA verifies the identity of the food facility, FDA will provide the facility access to its account.

Additional information on FDA food facility registration requirements, including FDA's food facility registration regulation, can be found on FDA's webpage at

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>.

Further, additional information can be found on FDA's webpage in the FDA Food Safety Modernization Act (FSMA) frequently asked questions section at

<http://www.fda.gov/food/guidanceregulation/fsma/ucm247559.htm#registration>.

Registrants may also find additional information on food facility registration requirements in the following resources:

Guidance for Industry: What You Need to Know About the Registration of Food Facilities – Small Entity Compliance Guide

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm>

Draft Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition) – Revised

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

For more information about these requirements, please refer to the guidance documents and frequently asked questions referenced in this update or contact the FURLS Helpdesk by phone at 1-800-216-7331 or 240-247-8804, or by e-mail at furls@fda.gov.

关于食品工厂是否需要支付注册费以及私人公司声称或暗示与 FDA 有隶属关系的问题

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美国食品药品监督管理局(FDA)仍不断收到食品工厂提出的关于食品工厂是否需要向 FDA 支付注册费用或通过第三方公司在 FDA 进行注册的问题。关于这些问题, FDA 明确食品工厂在 FDA 进行注册时不需要支付注册费用, 也不需要通过第三方公司或“登记人”在 FDA 进行注册。另外, FDA 了解有一些私人公司向食品工厂提供服务(如美国代理商登记和注册更新服务)。美国代理商可能会就他们提供的服务收取费用, 这应该是食品工厂和同意担任其代理的美国代理商之间需要决定的事情。FDA 希望提醒注册人 FDA 与这些私人公司没有任何隶属关系, 他们也不代表 FDA。

1. 《美国食品安全现代化法案》(FSMA)对《联邦食品、药品和化妆品法案》(FD&C Act)第 415 部分[21 U.S.C. § 350d]进行了修订, 新内容要求美国境内外生产、加工、包装、存储在美国境内所消费的人类食品和动物食品的工厂都须在 FDA 进行注册, 除非符合可以豁免的情况(请参考 21 CFR 1.226 部分)。需要在 FDA 进行注册的食品工厂必须通过官网、邮寄或传真方式直接在 FDA 进行注册。在 FDA 进行注册不需要任何费用(21 C.F.R. 1.231(c))。食品工厂可以自己在 FDA 的官方链接网页 <http://www.access.fda.gov> 进行注册、更新注册或取消注册(或授权其他人代为实施)。另外, 食品工厂也可以通过邮寄信件的方式进行注册、更新或取消注册, 相关表格可以通过拨打电话(美国境外拨打) 1-800-216-7331 或 240-247-8804 或通过发电子邮件至 furls@fda.gov 向 FDA 申请予以发送。FDA 将为成功注册的食品工厂分派一个注册号。任何已注册食品工厂可以通过联系 FDA 获取其注册号。
注: 根据《联邦食品、药品和化妆品法案》(FD&C Act)第 415 部分规定, 贸易商/经销商不需要注册。
2. 食品工厂不需要注册证书。FDA 不发放注册证书或产品类别(如低酸罐装食品), FDA 也不认可任何私人公司发放的注册证书或产品类别。如果有私人公司发放注册证书的情况, FDA 希望提醒发证人 FDA 的标识只能由 FDA 官方使用, 不能用于任何企业资料。对于公众来说, 对 FDA 标识的使用将或明确或暗示地传达 FDA 认可一个私人机构或机构的活动、产品、服务和/或人员的信息, FDA 不会也不能这么做。未经授权使用 FDA 标识可违反联邦法律, 相关责任人可受到民事和/或刑事处罚。关于使用 FDA 标识的更多信息, 请参考相关完整政策, 链接如下: <https://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ucm218116.htm>
3. 已经注册过但不知道自己的 FURLS 信息或密码的食品工厂不应该重新注册。食品工厂可以致电 1-800-216-7331 或 240-247-8804 或发电子邮件至 furls@fda.gov 联系 FDA 获得帮助。

FDA 将要求食品工厂用公司的抬头信纸并经公司所有人、经营人或授权代理人签字提供给 FDA 相关信息以便 FDA 进行核实。一经确认了食品工厂的真实身份后, FDA 将提供相关信息使工厂能登陆其注册帐户。

关于 FDA 食品工厂注册要求的更多信息，包括 FDA 食品工厂注册法规，可以在如下 FDA 的网页上找到

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>.

同时，FDA 网站上 FDA 《食品安全现代化法案》(FSMA)常见问题部分也有更多的相关信息。

<http://www.fda.gov/food/guidanceregulation/fsma/ucm247559.htm#registration>.

注册公司也可以通过如下资源得到关于食品工厂注册要求的更多信息：

行业指南：关于食品工厂注册你需要知道的内容—小工厂合规指南

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm>

行业指南暂行本：食品工厂注册问答（第七版）—修订版本

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

关于这些要求的更多信息，请参考本文中提到的指南文件和常见问题，或致电 1-800-216-7331 或 240-247-8804 或发电子邮件至 ~~furlis@fda.gov~~ 联系 FURLS 支持中心。