

FDA Food Safety Modernization Act and Registration of Food Facilities

FDA食品安全现代化法 食品企业设施注册

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Presentation Objectives

目的

- To provide information regarding food facility registration requirements as amended by the FDA Food Safety Modernization Act including:

提供FDA食品安全现代化法修订后，关于食品企业设施注册要求的信息，包括：

- Registration background 注册背景
- Additional registration information requirements 补充注册信息要求
- Registration renewal for food facilities 食品设施重新注册
- Suspension of food facility registration 吊销食品设施注册



FDA Food Safety Modernization Act

FDA食品安全现代化法

With the passage of the FDA Food Safety Modernization Act (FSMA) (Pub. Law 111-353), domestic and foreign manufacturers, processors, packers or holders of food for human or animal consumption in the United States must comply with new statutory requirements

FDA食品安全现代化法（FSMA）(Pub. Law 111-353)出台后，生产，加工，包装或储存供美国人和动物消费的食品的国内和海外企业设施必须遵守新法令要求。



Food Facility Registration

食品设施注册

- Food facilities subject to section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) were required to register with FDA before December 12, 2003

联邦食品药品化妆品法案（FD&C Act）415部分所说的食品设施是指那些被要求在2003年12月12日以前在FDA注册的设施

- A food facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003 must register before the facility begins such operations (21 CFR 1.230)

食品设施进行生产/加工，包装或储存的食物，如果在2003年12月12日或以后在美国消费，必须在企业开工前进行注册（21CFR 1.230）

Food Facility Registration

食品设施注册

- If a change occurs to a facility's previously submitted required registration information, such facility must update its registration to reflect the change within 60 calendar days of the change, except for a change of the owner (21 CFR 1.234)

如果以往提交的注册信息发生变化，该设施必须在变化后60个日历日内更新注册信息，设施所有者变更除外。

- If a facility has a new owner, the former owner must cancel the facility's registration within 60 calendar days of the change and the new owner must submit a new registration (21 CFR 1.234)

如果设施异主，前所有者需要在发生变化后60个日历日内注销注册信息，新所有者重新提交注册（21 CFR 1.234）

Changes to Food Facility Registration Under FSMA

食品安全现代化法中食品设施注册变化

- FSMA amended section 415 of the FD&C Act to require in relevant part that facilities engaged in manufacturing, processing, packing, or holding food for human or animal consumption in the U.S. submit additional registration information to the FDA
- 食品安全现代化法关于FD&C Act第415部分修订的有关部分要求从事生产，加工，包装或储存在美国人或动物消费的食品的设施需要向FDA提交补充注册信息。

Additional Registration Information Required

补充注册信息要求

- The e-mail address for the contact person of the facility or, in case of a foreign facility, the email address of the U.S. Agent for the facility

设施联系人的电子邮件地址。对于海外设施，提供美国代理人的电子邮件地址

- Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act

确保同意FDA在指定时间按照FD&C Act允许的方式对企业设施进行检查

- If determined necessary and appropriate by FDA, updated food category information

如果FDA认为必要和合理，更新食品分类信息

Biennial Registration Renewal

每两年重新注册

- FSMA also amended section 415 of the FD&C Act to provide that food facilities required to register with FDA must renew their registrations with FDA every two years, between October 1 and December 31 of each even-numbered year

食品安全现代化法关于FD&C Act第415部分修订提出在FDA注册的食品企业必须每两年重新注册，时间为每偶数年的10月1日到12月31日之间

- *We note that biennial registration renewal for food facilities is currently unavailable. Please check FDA's website at www.access.fda.gov at a later date or sign up for FSMA updates at www.fda.gov/FSMA to be informed when it becomes available.*

我们注意到目前食品企业每两年重新注册还未实施。请稍候关注FDA网站www.access.fda.gov，或登陆FSMA更新网站www.fda.gov/FSMA 获取何时开始实施的信息。

- At this time, the same types of food facilities that were required to register with FDA under section 415 of the FD&C Act before FSMA are required to register with FDA and renew such registrations

目前，在实施FSMA之前根据FD&C Act第415部分需要在FDA注册的食品设施仍然需要在FDA注册和重新注册信息。

Registration Renewal

重新注册

- Registrants are required to submit renewal registrations to FDA containing the required registration information, including the new information
- 已经注册的需要向FDA提交重新注册信息，这些信息包括新增加的补充信息。



Registration Renewal Process

重新注册程序

- Registrants can submit registration renewals at any time during the renewal cycle, using the online food facility registration module or paper Form FDA 3537

注册企业可以在重新注册时限内任何时间提交重新注册，可以通过企业在线注册模式或纸质FDA3537表提交注册。

- Online, registrants will have the opportunity to review and edit existing registration information and add additional information

通过在线方式，注册企业将有机会审核和编辑已有注册信息并添加补充信息

- Note that all information submitted to FDA must be true and accurate, but only mandatory data fields are required to complete the renewal process

需要注意的是，向FDA提交的所有信息必须真实准确，重新注册时只要填写必填项

Registration Renewal Process

重新注册程序

- FDA will accept registration submissions, including initial registrations, updates of registration information, and biennial registration renewals via online entry, mail, fax, or CD-ROM for multiple submissions.

FDA接受通过网上账户/邮寄/传真/CD-ROM光盘形式向FDA提交注册/对现有注册内容更新/以及两年一次的重新注册。

- There is no fee to register, update, renew, or cancel the registration of a food facility

食品设施的注册/更新/重新注册/取消注册都是免费的。

- Facilities will retain their existing registration number when successfully completing registration renewal process

已注册食品设施在成功完成重新注册后将保留现有注册号。

Failure to Register

不依法注册

- The failure to register your facility, update required elements, or cancel a registration in accordance with FDA's registration regulation (21 CFR 1.225-1.243) is considered a prohibited act under the FD&C Act (21 CFR 1.241)

依据美国联邦食品药品化妆品法案 (21 CFR 1. 241), 食品设施如不依法(21 CFR 1. 225 – 1. 243)注册/更新规定的注册内容/取消注册, 被视为禁止行为。

- Additionally, if a foreign food facility fails to register in accordance to FDA's registration regulation, food from that facility that is being imported or offered for import into the U.S. may be subject to refusal (21 CFR 1.241(c) and 1.285)

此外, 海外设施如不依照FDA法规注册, 其输美产品将被拒绝入境 (21 CFR 1.241(c) 和1.285).



Suspension of Registration

吊销注册

- Section 415(b) of the FD&C Act, as amended by FSMA, also provides FDA with authority to suspend the registration of a food facility in certain circumstances

依据食品安全现代化法案修改后的联邦食品药品化妆品法案415(b)授权FDA在某些情况下可吊销食品设施的注册。

- Prior to FSMA, FDA did not have the authority to suspend the registration of a food facility in such circumstances

在食品安全现代化法案生效前，FDA无权在这些情况下吊销食品设施的注册。



Suspension of Registration

吊销注册

- Under section 415(b) of the FD&C Act, if FDA determines that food manufactured/processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

依据食品药品化妆品法案415(b), 如FDA判定在某设施生产/加工/包装/收受/存放的食品有合理的可能性导致人或动物产生严重健康危害或死亡, FDA可下令吊销该设施的注册。该设施:

- Created, caused or was otherwise responsible for such reasonable probability; OR

已产生/已导致该合理的可能性或者是该合理可能性的责任方

- Knew of or had reason to know of such reasonable probability AND packed, received or held such food.

已知悉/有理由知悉该合理可能性, 并已包装/已收受或已存放该食品



Suspension of Registration

吊销注册

- FDA will provide a registrant subject to an order of suspension of registration with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of a suspension order, unless an alternate time period is agreed upon by FDA and the registrant

对适用注册吊销令的注册人，FDA可提供一次非正式的聆讯机会。该聆讯可在吊销令签发后尽快但不多于两个工作日内进行，除非FDA和注册人协定在另一时间进行。

- If the registration of a facility is suspended, no person can import or export food into the United States, offer to import or export food into the United States, or otherwise introduce food into interstate or intrastate commerce in the United States from such facility

对于吊销注册的设施，任何人不能将来自该设施的食品进口或出口到美国，不能提供该设施食品用于进口/出口到美国，以及不能将该设施的食品引入美国的州际和州内商业贸易。

Conclusions

总结

- Food facility registrations must be renewed every two years

食品设施必须每两年重新注册

- Biennial registration renewal for food facilities is currently unavailable. Please check FDA's website at www.access.fda.gov at a later date or sign up for FSMA updates at www.fda.gov/FSMA to be informed when it becomes available

食品设施每两年重新注册目前尚未开始。请稍后查阅FDA注册网站 www.access.fda.gov 或登录 www.fda.gov/FSMA 以便及时收到更新信息通知。

- Additional information is now required for initial registration and renewal of food facility registration

首次注册和重新注册现在要求提交更多信息

- FDA now has authority to suspend a food facility registration under certain circumstances

FDA现在有权在某些情况下吊销食品设施的注册



For More Information 如需更多信息

- Visit www.fda.gov/fsma
 - For additional guidance
登录www.fda.gov/fsma查阅其他指南
- Subscribe to the FSMA Mailing List
网上订阅FSMA更新通知
- Email 电邮 fsma@fda.hhs.gov
- Call 电话
(001) 800-216-7331
or (001) 301-575-0156

