

**T.C.**  
**VAŞINGTON BÜYÜKELÇİLİĞİ**  
**Ticaret Müşavirliği**

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**Sayı : 72520227 / 310**  
**Konu : FDA Kayıt İşlemleri**

**EKONOMİ BAKANLIĞINA**  
**(İhracat Genel Müdürlüğü)**

Amerika Birleşik Devletleri Gıda ve İlaç İdaresi tarafından 21 Ekim 2014 tarihinde FDA'e kayıt işlemleri ile ilgili yayımlanan duyurunun bir örneği ekte gönderilmektedir. Anılan duyuruda özetle; ABD'ye gıda ürünü ihraç edecek firmaların FDA'e kayıt işlemlerinin ücretsiz olduğu ve sözkonusu işlemlerin aracı bir firmaya gerek olmaksızın yapılabileceği belirtilmektedir.

Bilgilerine arz olunur.



**Ömür DEMİR KIZILARSLAN**  
**Ticaret Başmüşaviri**

**EK:**

- Duyuru Örneği (2 sayfa)

**DAĞITIM:**

- İhracat Genel Müdürlüğü
- Anlaşmalar Genel Müdürlüğü



U.S. Food and Drug Administration



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

October 21, 2014

The United States Food and Drug Administration (FDA) has received a significant number of questions from food facilities regarding whether such facilities are required to pay registration fees or use third-party businesses in order 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, such as "FDA Registrar Corporation" (FDA Registrar Corp.), are offering services (such as U.S. agent listing and registration renewal services) to food facilities. FDA would like to remind registrants that FDA is **not** affiliated with these private businesses, nor do they act on FDA's behalf.

1. Food facilities that are required to register with FDA must register directly with FDA electronically, by mail or fax, or by CD-ROM for multiple submissions (21 C.F.R. 1.231). There is no fee to register with FDA (21 C.F.R. 1.231(d)).

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 301-575-0156 outside the United States, or by e-mail at [furls@fda.gov](mailto:furls@fda.gov).

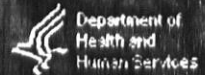
U.S. Agents may charge a fee for their services, which is solely an issue to be decided between the food facility and the person who agrees to serve as the food facility's U.S. Agent.

2. Contrary to any suggestion by FDA Registrar Corp., food facilities do not need a certificate of registration. FDA does not issue a certificate of registration, nor does FDA recognize a certificate of registration issued by a private business. FDA issues a registration number to registered food facilities. Any registered food facility may obtain its registration number by contacting FDA.
3. Contrary to any suggestion by FDA Registrar Corp., food facilities that have registered and do not have their FURLS information or PIN should not re-register. Instead, a food facility can contact U.S. FDA for help at 1-800-216-7331 or 301-575-0156, or by e-mail at [furls@fda.gov](mailto: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.



## U.S. Food and Drug Administration



Additional information on FDA food facility registration requirements, including FDA's food facility registration regulation, can be found on FDA's webpage at [www.fda.gov](http://www.fda.gov). Further, additional information can be found on FDA's webpage in the FDA Food Safety Modernization Act (FSMA) frequently asked questions section, specifically questions IC.3.8 and IC.3.11, at

<http://www.fda.gov/food/guidanceregulation/fsma/ucm247559.htm#registration>. Registrants may also find additional information on food facility registration requirements in *The Guidance for Industry: What You Need to Know About the Registration of Food Facilities – Small Entity Compliance Guide* and *The Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)*. These guidance documents were last updated in December of 2012 and provide information on current registration requirements.

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 301-575-0156, or by e-mail at [furl@fda.gov](mailto:furl@fda.gov).