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PBB GLOBAL LOGISTICS – FACT SHEET

The FDA's New Regulatory Framework

Key Facts & Figures

Enabling Legislation:

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Implementation Date:

December 12, 2003 (interim rules)

Final Rules Published:

December 9, 2004

Businesses Affected:

400,000 (U.S. and foreign)

Further Information:

www.fda.gov/oc/bioterrorism/bioact.html

Overview

On December 12, 2003, new Food & Drug Administration (FDA) regulations governing the importation of food into the U.S. came into effect. As the primary authority over food in the U.S., the FDA aims to strengthen its ability to protect the nation's food supply from potential bio-terrorism threats.

Most businesses involved in the country's food supply, whether domestic or foreign, are affected by one or more initiatives. This includes companies involved in manufacturing, processing, packaging or holding food. Truck terminals and freight forwarders that are part of the transportation network and only have possession, custody or control of food for the sole purpose of facilitating its transport, however, are not required to register. Food itself is broadly defined as "articles for food or drink for man or other animals... chewing gum.... and other articles".

Details

Mandated under Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the FDA uses four primary mechanisms to improve its ability to regulate the industry:

1. Registration of food facilities

All food facilities that operate in or export to the U.S. must be registered with the FDA. Estimates suggest that 400,000 facilities are affected by this requirement.

2. U.S. agent requirement

As part of the registration process, all foreign facilities must appoint a U.S. based agent for purposes of communication with the FDA.

3. Prior notice

Import data must be transmitted to the FDA two to eight hours prior to arrival at the border, depending on the mode of transportation. This gives the FDA sufficient time to evaluate potential risk and identify shipments for inspection and possible detention.

4. Recordkeeping requirements

To improve the FDA's investigative abilities, affected businesses are required to create and maintain certain records for a period of up to two years.

PBB FACT SHEET

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Date: March 2005





The FDA's New Regulatory Framework

CONTINUED

How to appoint PBB as your FDA Agent:

- Download the Agency Agreement and Appendix A directly from the website.
- Sign and fax a copy to PBB's TRS Department at (716) 696-5554.
- Forward the originals by mail to TRS at our Tonawanda, NY office.
- Once registration has been completed, forward a copy of the registration form and the accompanying registration number to PBB.

FDA Registration

Registration is now open and can be carried out on-line on the FDA website at www.access.fda.gov. As all the information contained in the registration must be certified to be true and correct, foreign food facilities should register themselves.

Choosing an FDA regulatory agent:

Businesses that export food products for human or animal consumption to the U.S. are required to engage a U.S. resident agent before they are able to register their facility/facilities with FDA.

Role of the agent:

- Help non-U.S. clients fulfill their regulatory requirements to obtain a U.S. agent.
- Assist the client in communications with the FDA.
- Facilitate information and/or documentation exchange between the FDA and the client.
- Help resolve problems.
- Serve as 24/7 emergency contact for FDA on behalf of the client.
- Advise on preventing or minimizing penalty situations.
- Represent the client in the event of penalties/detentions.
- Maintain documentary and communication records relating to U.S. agency functions if these are required.

How PBB can help your business:

To maintain your access to key U.S. markets, your choice of agent is critical. Thanks to our customs brokerage and logistics expertise, PBB is ideally positioned to serve as U.S. agent for your business' dealings with the FDA. PBB offers:

- A single point of contact for cross-border shipments.
- Efficient handling of the prior notice process, since we already handle shipment details for customs purposes.
- Effective representation, based on a long history of working with the FDA.
- Up-to-date information and insight on related topics, leveraging PBB's association with many government and industry organizations to your advantage.

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