BLA REGULATORY

PHARMAFOCUS

Weekly Newsletter - One Topic at a Time

2025 wk-issue 01, 24 Jan. 2025

About Us

BLA Regulatory is located in the State of Maryland, conveniently close to the FDA's headquarters. We offer U.S. agent services for all types of FDA-regulated products, including drugs, cosmetics, medical devices, and more. Our team can guide you through the entire application and registration process to ensure FDA compliance. Please visit our office website for more information or if you need any assistance.

U.S. Agent for FDA Regulated Product Applications

Pursuant to USA's Code of Federal Regulations 21 § 207.69(b), any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of FDA-regulated products (such as drugs, medical devices, food, or cosmetics) imported into the United States is required to designate a U.S. agent. The U.S. agent must reside or operate a business within the United States and cannot be a mailbox, answering service, or any location where the agent is not physically present.

For Investigational New Drug (IND) applications, the U.S. agent is authorized to represent the foreign sponsor before the FDA. The U.S. agent acts as a liaison, facilitating communications, responding to inquiries about the foreign establishment's products, aiding inspection processes, and receiving documents and information from the FDA on behalf of the foreign entity. Foreign pharmaceutical companies may appoint a U.S. agent during the eCTD submission process, with a separate letter of appointment required.

In general practice, the U.S. agent designation must be submitted electronically through the FDA Unified Registration and Listing System (FURLS) as part of the foreign establishment's registration. A foreign establishment may designate only one U.S. agent, whether or not the agent is also named as the official correspondent. The foreign establishment must provide the U.S. agent's name, address, phone number, fax number, and email address. After designation, the U.S. agent must complete an automated process to confirm their agreement to act in this capacity. The FDA system will send a verification email to the U.S. agent requesting confirmation of their consent. If the U.S. agent declines or fails to respond within 10 business days, the foreign establishment's Official Correspondent or Owner/Operator will be notified and must select a new U.S. agent to comply with regulatory requirements.

References:

- U.S. Agents. https://www.fda.gov/medical-devices/device-registration-and-listing/us-agents
- US Agent Verification Initiative. Leyla Rahjou-Esfandiary. (2021). https://www.fda.gov/media/154513/download