U.S. Agents and Official Contacts

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Agenda

- U.S. Agent Requirements
- Official Contacts
- U.S. Agent Verification
- Next Steps
- Adverse Actions
- Useful Tips

Learning Objective

- Upon completion of this presentation:
- Describe the requirements of a U.S. Agent and Official contact
- Comprehend verification requirements
- Identify adverse actions

U.S. Agent Requirements

Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug imported into the United States must identify a United States agent (U.S. agent) for that establishment. Outlined in 21 CFR § 207.69(b)

U.S. Agents Requirements

- 21 CFR 207.69(b)
  - Registrants of foreign establishments subject to this part must designate a single United States agent.
  - The United States agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent is not physically present.

U.S. Agent Requirements

- Responding to questions concerning those drugs that are imported or offered for import to the United States
- Assisting FDA in scheduling inspections
- Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications
- If FDA is unable to contact a foreign registrant directly or expeditiously, FDA may provide the information and/or documents to the United States agent.
- FDA's providing information and/or documents to the United States agent is equivalent to providing the same information and/or document to the foreign registrant.

Official Contact

Registrants subject to the registration requirements of 21 CFR part 207 must designate an official contact for each establishment. The official contact is responsible for:

(1) Ensuring the accuracy of registration and listing information; and

(2) Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications.

Verification

- FDA may contact U.S. agents for new labeler code assignments, registration and listing deficiencies, amongst other reasons
- If we have reason to believe U.S. agent information on Labeler Code SPL or Registration SPL is not accurate and up-to-date:
  - Open a compliance case
  - Send a deficiency letter

Verification

- U.S. agent data is published online within registration data: Drug Establishment Current Registration Site
  - Downloadable file
  - Zip format
- FDA has been contacted about some unauthorized use

U.S. Agent Deficiency Letter

POSSIBLE LABELER CODE/ REGISTRATION INACTIVATION

Greetings,

A recent review and verification of your Labeler Code SPL by the Food and Drug Administration's Drug Registration and Listing Office has revealed inaccurate U.S. Agent data or an inaccurate designation of U.S. Agent for the labeler identified below.

Labeler Code	Labeler Name	US Agent Duns	US Agent Name	US Agent Email	US Agent Phone

The entity identified above has stated to the FDA that they do not act as the US agent for the labeler code assignee. Under section 510(i)(1) of the Federal Food, Drug and Cosmetic Act (FD&C Act), every person who owns or operates any establishment within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States is required to register with the FDA and provide the name of the U.S. Agent for that establishment. (21 U.S.C. 360(i)(1)(A)(i)). Further, the Code of Federal Regulations, at 21 CFR 207.69, requires that the U.S. Agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the U.S. Agent is not physically present.

Accurate and complete U.S. Agent information is required by FDA to facilitate important and timely communication with a foreign labeler or registered establishment. Under 21 CFR 207.29(a)(3), registrants are required to update their registration no later than 30 calendar days after changing the name, address, telephone number or email of a U.S. Agent. Please either update your labeler code and/ or registration with accurate U.S. Agent information or inactivate your labeler code and/ or deregister the establishment within 30 days of the date of this email. Failure to do so may result in the inactivation of your labeler code and/ or establishment's registration.

A drug that was manufactured in an establishment not duly registered under section 510 is misbranded under Section 502(o) of the FD&C Act. (21 U.S.C. 352(o)). Introduction or delivery for introduction into interstate commerce of a misbranded drug is unlawful under Section 301(a) of the FD&C Act (21 U.S.C. 331(a), 352(o)). Further, any drug offered for import that appears to be misbranded may be detained or refused admission under Section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)).

This letter notifies you of our concerns and provides you an opportunity to address them. If you believe that your products are not in violation of the FD&C Act, please respond within 30 days of the date of this email and provide your reasoning and any supporting information.

If you have questions about this letter or require assistance in updating your registration, please contact our Drug Registration and Listing helpdesk at edrls@fda.hhs.gov

Drug Registration and Listing Staff

Next Steps

- New U.S. agent?
  - Update Labeler Code SPL
  - Update Registration SPL
- No longer manufacture/ import drugs for U.S. commercial distribution?
  - Deregister with FDA
  - Delist drugs (with last lot expiration date)
  - Inactivate labeler code

Adverse Actions

- Drug listing and labeler code inactivation
- Establishment registration inactivation
- FDA-initiated inactivation can only be reversed by FDA
- Industry-initiated labeler code inactivation can be reversed by industry if/ when manufacturing and importing drugs resume

Useful Tips

- A change in U.S. agent should be reported through Labeler Code SPL and/ or Registration SPL
- U.S. agents must assume all responsibilities outlined in 21 CFR § 207.69(b)
  - Submission vendors included as U.S. agents must assume all U.S. agent responsibilities
- Official contact and U.S. agent are different entities
  - U.S. agent is based in U.S. and official contact is the responsible person at the establishment for communicating with FDA
- Do not ignore verification and deficiency letters

Challenge Question

My Drug establishment develops hand sanitizer located in Tokyo, Japan. I want to import my product to the United States. What CFR is the requirements listed under?

A) 21 CFR § 207.69(b)

B) 21 CFR § 207.96(b)

C) 21 CFR § 209.67(c)

D) CFRs are only suggestions

Challenge Question

My Drug establishment has a new US agent. What do I need to do?

A) Ensure the US Agent knows the CFRs
B) Call the FDA and report the US Agent info
C) Update Labeler/Registration SPL
D) Continue business operations as usual

References

- § 207.69 What are the requirements for an official contact and a United States agent?
- https://www.ecfr.gov/current/title-21/section-207.69

Questions?

eDRLS@fda.hhs.gov