

US Agent Verification Initiative

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Agenda

- US Agent requirements and responsibilities
- Pandemic and its challenges
- US Agent verification and verification initiative
- What to do next?
- What happens next if correction is not made?
- Useful tips





US Agent Requirements

- Required for all registered foreign drug manufacturing establishments
- Outlined in 21 CFR § 207.69(b)
 - Only one agent per registered establishment
 - Must reside in the US



US Agent's Responsibilities

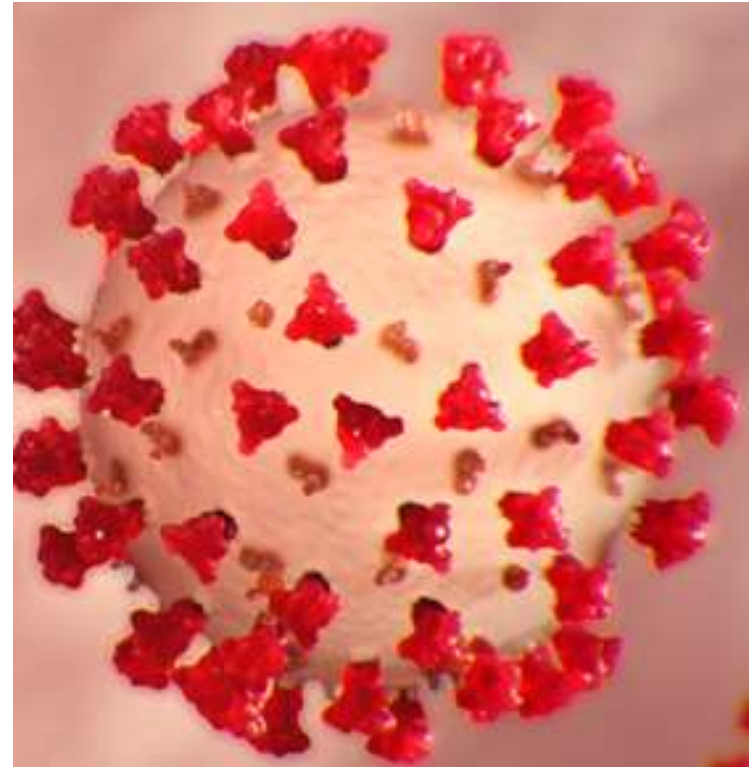
- Responsible for all communications from FDA including emergency communications;
- Responding to questions concerning imported drugs;
- Assisting FDA in scheduling inspections; and
- Receiving information and documents from FDA on behalf of a foreign registrant.



Coronavirus Disease 2019 (COVID-19)



- Declared a national public health emergency on January 31, 2020
- Influx of new labeler code requests, registration and listing data submissions





US Agent's Challenges

- Difficulty reaching the registrants at a crucial time
- US Agent wasn't "really" a US Agent
- US Agent wasn't a US entity or business
- Unauthorized inclusion of US Agent on registration SPL





Published Data

- US 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





Verification Initiative

- FDA contacts US Agents for new labeler code assignments, registration and listing deficiencies, amongst other reasons
- If we have reason to believe US Agent information on Labeler Code SPL or Registration SPL is not accurate and up-to-date:
 - Open a compliance case
 - Send a deficiency letter



US 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



What to Do Next?

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



Lack of Action

- 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 US Agent should be reported through Labeler Code SPL and/ or Registration SPL
- US Agents must assume all responsibilities outlined in 21 CFR § 207.69(b)
- Official contact and US Agent are different entities
- Do not ignore our verification and deficiency letters!





Questions?

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