Case Study of a Violation

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Learning Objectives

- Troubleshoot establishment registration and drug listing issues
- Identify and fix validation errors in submitted SPL files

Case Study Procedures

- After introduction of case, review the case study packet for answers
- Chat is available for questions or clarifications
  - Do **NOT** post answers in chat
- We will discuss the answer later in the presentation

Case Study #1 – Hand Sanitizer

- You receive a deficiency letter from FDA
  - What is the deficiency stated in the letter?
- What steps do you take to resolve the deficiency?

Case Study #1 – Answer

- Wrong active ingredient and strength

1. Review listing and look for specific issue
2. Correct specific issue, but also take the time to review the rest of the listing for accuracy
3. Save and validate
4. Submit SPL
5. Follow the procedure for a manual override (as needed)

Case Study #2 – Inactivation

- You receive a deficiency letter from FDA
  - What is the deficiency stated in the letter?
- What steps do you take to resolve the deficiency?

Case Study #2 – Answer

- Listing contains a non-registered establishment

1. Review establishment(s) in listing
2. Verify that the listing contains all the current facilities that are part of the manufacturing process
3. Verify that all the cited establishments are duly registered
4. Submit an updated establishment registration for any non-renewed registrations or contact the establishment and notify them of the need to register

Summary

- Registration and listing information is used throughout FDA to support programs such as drug shortages, inspections, and supply chains
- Consumers and healthcare providers use it for drug information
- Accurate data benefit EVERYONE!

Questions?

Compliance questions: edrls@fda.hhs.gov

Technical questions: cderdirect@fda.hhs.gov

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