Drug Registration and Listing Compliance Program

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October 2021
Agenda

• Program overview
• Case progression
• Registration and listing data
• Our approach
• Our compliance projects
• Helpful tips and links
Regulations

• Included in Section 510 of the Food, Drug and Cosmetic Act


• Outlined in 21 CFR Part 207

https://www.ecfr.gov/cgi-bin/text-idx?SID=fa8d7e9c3c27e094261bf903b897eb6e&mc=true&node=pt21.4.207&rgn=div5#se21.4.207_117
Compliance Program Overview

• Began in 2015
• Focuses on registration and listing data integrity and accuracy
• Phases:
  – Surveillance
  – Deficiency letter
  – Data removal
  – Final action: untitled letter, warning letter, data inactivation
Case Progression

The Power is Yours

- Deficiency Letter
  - Correction
  - Case Closed

- Deficiency Letter
  - Correction
  - Data Removal
  - Case Closed

- Deficiency Letter
  - Correction
  - Data Removal
  - UL, WL, Data Inactivation
  - Case Closed
Drug Listing Data

Currently Listed Drugs

- Human OTC: 74,567
- Human Rx: 54,929
- Bulk Ingredient: 3,406
- Drugs for Further Processing: 3,348
- Biologics: 3,811
- Animal Drugs: 15,696

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Registration Data

Currently Registered Establishments

- Manufacturer and API Manufacturer: 10717
- Packager and Repackager: 2873
- Labeler and Relabeler: 3035
- Analysis: 2940

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Our Approach

• Risk-based approach
• Public health and patient safety
• Cooperative operations
• Large projects
  – Product/ ingredient
  – Certain business types
  – FDA actions and initiatives
Our Compliance Projects

• Annual January and July Drug Listing Inactivation Project
• US Agent Project
• Alcohol-Based Hand Sanitizers Project
• Chloroquine/ Hydroxychloroquine Labeling Project
• Labeler Code Inactivation Project
Why Pay Attention?

• In addition to compliance with the registration and listing requirements:
  – Import disruption
  – Reimbursement issues
  – Labeling removal from DailyMed
  – Adversely affecting business
  – Most importantly: patient access and patient safety consideration
Useful Tips

• Hire the right people
• Attend annual workshops
• Learn about the requirements: existing and upcoming
• Submit the complete and accurate data THE FIRST TIME AROUND
• Review registration and labeler contact info
• Don’t ignore our deficiency letter
Helpful Links

  - Drug listing inactivation Federal Register
  - Strength conversion in drug listing
  - CDER’s application of the USP salt policy
Remember: The Power is Yours!

Questions?

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Thank You!