Drug Registration and Listing Compliance Program

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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

  https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360.htm

- Outlined in 21 CFR Part 207

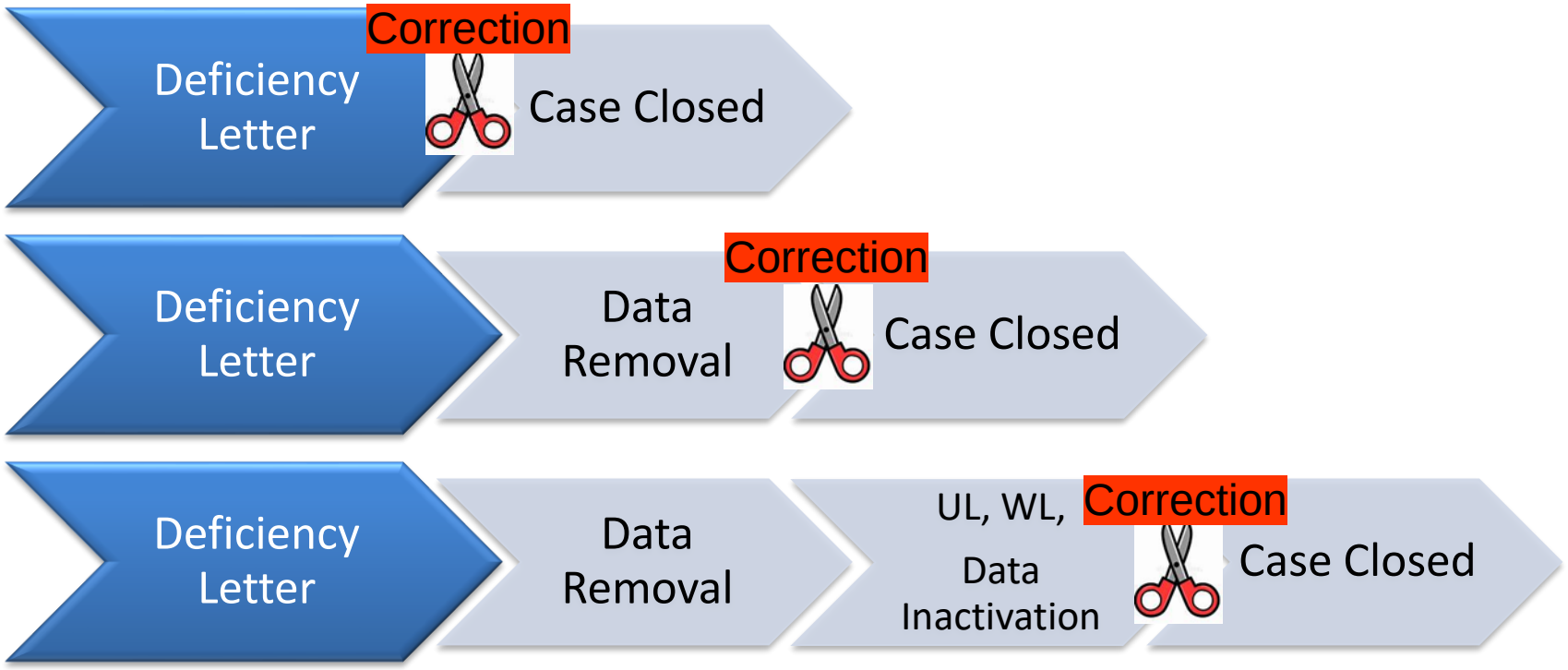
  https://www.ecfr.gov/cgi-bin/text-idx?SID=fa8d7e9c3c27e094261bf903b897eb6e&mc=true&node=pt21.4.207&rgn=div5#se21.4.207_117

Compliance Program Overview

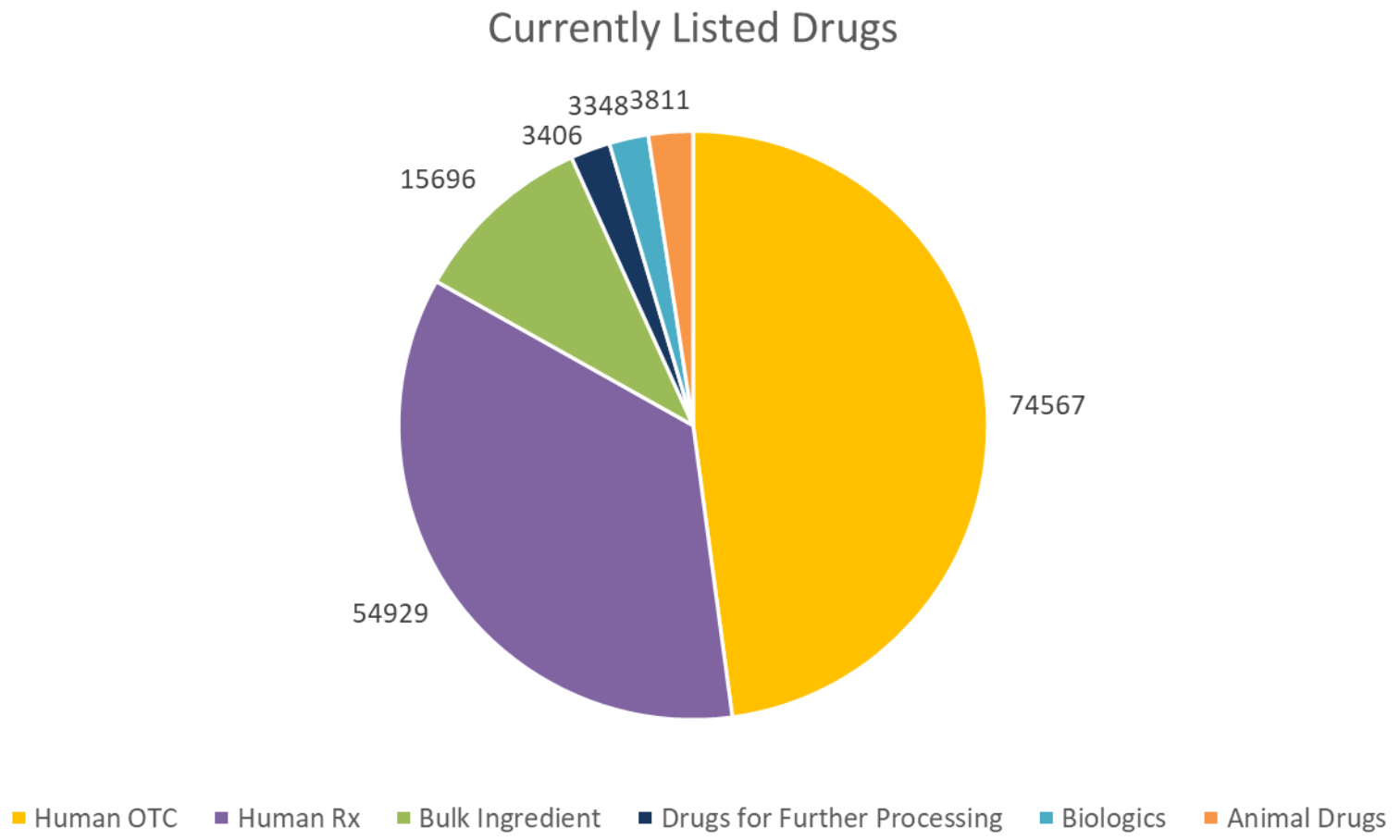
- Began in 2015
- Focuses on registration and listing data integrity and accuracy
- Phases:
  - Surveillance
  - Deficiency letter
  - Data removal
  - Final action: untitled letter, warning letter, data inactivation

Case Progression

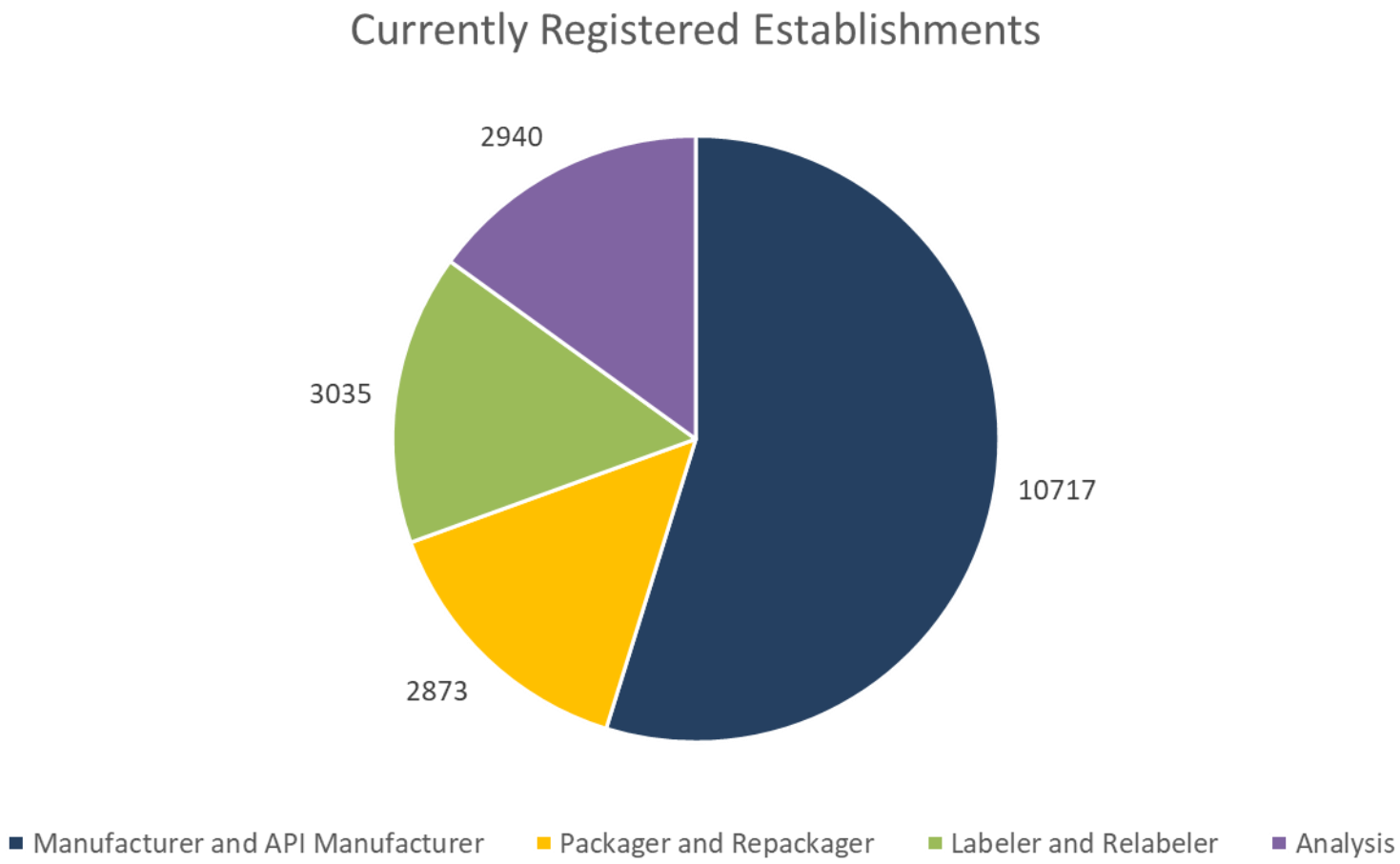
The Power is Yours



Drug Listing Data



Registration Data



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

- https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-registration-and-listing-compliance-program
  - 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!