FDA Sampling Guidance and Practices

Terri McConnell
FDA/ORA/Office of Regulatory Science
Background and General Information

- Mission of the Food and Drug Administration (FDA)
- Major Laws Enforced by the FDA
- Evidence and sample Chain of Custody Considerations
- Accepting State Data
Mission of FDA

- Promote the public health by ensuring that
  - Foods are safe, wholesome, sanitary, and properly labeled
  - Human and veterinary drugs are safe and effective
  - Medical devices intended for human use are safe and effective
  - Cosmetics are safe and properly labeled
  - Public health and safety are protected from electronic product radiation
- FDA is a regulatory agency
Major Laws Enforced by FDA

- Food, Drug, and Cosmetic Act, as Amended (FD&C Act)
- Public Health Service Act (PHS)
- FDA Food Safety Modernization Act (FSMA)
What Does FDA Regulate?

- **Biologics**: Viruses, Antitoxins, Vaccines, Blood/Blood Components
- **Cosmetics**
- **Foods**: Labeling, Safety of food products (except meat and poultry), Bottled water
- **Human Drugs**: Product Approvals, Over-the-Counter (OTC) and Prescription Drug Labeling, Drug Manufacturing Standards
- **Medical Devices**
- **Radiation-Emitting Electronic Products**: microwave ovens, TVs, diagnostic X-ray equipment, laser products, sun lamps, mammography facilities
- **Veterinary Products**: Livestock and Pet food, Veterinary drugs and devices.
What FDA Does Not Regulate

- Advertising for products other than drugs or medical devices. The Federal Trade Commission regulates advertising for all other products.
- Alcohol: Regulated by Bureau of Alcohol, Tobacco, Firearms and Explosives
- Meat and Poultry: Regulated by the US Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS)
- Pesticides: The Environmental Protection Agency (EPA) determines safety and effectiveness of pesticides and establishes tolerance levels
- Restaurants and Grocery Stores
- Municipal drinking water: Regulated by EPA
FDA Legal Considerations

- FDA authority is outlined in our regulations
- Compliance/Regulatory Action elements
  - Jurisdiction
  - Interstate Commerce
  - Violation
  - Responsibility
- This information is provided by developing evidence to support a legal case
- Regulatory samples are part of this evidence
Chain-of-Custody Definition

- The movement and location of physical evidence from the time it is obtained until the time it is presented in court.

http://legal-dictionary.thefreedictionary.com
Chain of Custody Elements

- What was collected?
- Who collected it?
- When did they collect it?
- How did they collect it?
- Where did they collect it?
- Who did they give it to?
- What did they do with it?
- Who else has had access to it?
- What is it’s current condition?
- Where is it now?
Things to Consider

- How is chain of custody documented?
  - Are there specific forms or procedures that your customer uses for chain of custody?

- Physical security elements (locked storage, seals, etc.)

- Environmental storage conditions

- Other issues: Some products (controlled substances, select agent cultures, etc.) require additional security measures.
Things to Consider

- Chain of custody starts as soon as the sample is collected.
- These issues need to be sorted out before the sample is collected.
FDA Procedures

- Domestic Compliance Samples are sealed
- Chain-of custody maintained electronically in an internal system as well as by hard copy documentation (analytical worksheets).
- Sample reserves are re-sealed and securely stored pending final disposition determined by FDA District Compliance Office.
FDA Official Sample Seal
FDA Acceptance of State Data

- FDA/ORA is currently participating in initiatives involving state data acceptance:
  - Partnership for Food Protection (PFP) Laboratory Best Practices
  - Data Acceptance Workgroup

- Partnering with APHL, AFDO, AFCO and state laboratories on these initiatives

- Developing Data Acceptance Criteria that can be used as a tool by non-ISO 17025 Accredited Laboratories
Examples of FDA Use of State Data

- **2014-2015: Large Scale Avocado Sampling Assignment**
  - 15 FERN microbiology laboratories assisted with analyzing samples from this assignment
  - Samples were collected by FDA investigators and sent to state servicing labs
  - Analytical documentation for positive samples submitted to FDA and reviewed by agency SMEs
Official Avocado Sample
Future Considerations

- Continued support of developing processes for accepting state data
- Finalize data acceptance criteria document to serve as a tool for state laboratories
- Major Challenge
  - Electronic data sharing
References/Additional Information

- FDA/ORA Laboratory Manual, Chapter 2
  - http://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/default.htm

- FDA Investigations Operations Manual
  - http://www.fda.gov/ICECI/Inspections/IOM/

- PFP Food/Feed Testing Laboratory Draft Best Practices
  - http://www.fda.gov/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/default.htm
Contact Info

CDR Terri T. McConnell, USPHS
FDA, ORA, Office of Regulatory Science
60 8th St. NE
Atlanta, GA 30309
Office: 404-253-1217
Fax: 404-253-1207