

**Food and Drug
Administration**

vs.

**South American Regulation;
How do they Compare?**

Presented by: Anna Turbyfill

Advisor: Dr. Ann Ortiz

Honors Program Senior Thesis

FDA: How it came to be

- 1906, Pure Food and Drug Act, Meat Inspection Act
- 1912, Sherley Amendment
- 1930, name changed to Food and Drug Administration
- 1938, Federal Food Drug and Cosmetic Act
- 1958, The GRAS Listing, Food Additives Amendment
- 1962, Kefauver-Harris Drug Amendments

FDA: Why it changed

- ⦿ Unsanitary conditions
- ⦿ Unpredictable contents
- ⦿ Lack of cleanliness
- ⦿ Disaster
- ⦿ Social reform
- ⦿ Economic drive
- ⦿ Political culture

FDA: What it is today

- ⦿ Mission: Protect the public health by ensuring efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- ⦿ Regulations

Brazil: Ministry of Health

- ⦿ 1808, Public Health
- ⦿ 1953, Ministry of Health
- ⦿ 1990, National Congress of Brazil approved the Organic Health Law
- ⦿ Strict regulatory enforcement
 - Documentation
- ⦿ AGEVISA
 - Import Approvals

Argentina: ANMAT

- ⦿ 1992, Established by decree
- ⦿ Numbered regulations
 - Unenforced
- ⦿ Import documentation
- ⦿ Labels in Spanish
- ⦿ Quality checks

Peru: DIGEMID

- ⊙ Regulations
 - Numbered
 - Enforced regarding bids
 - Unenforced regarding medical products
 - Commercialization
- ⊙ Counterfeit Medications
- ⊙ Import licensure

General Similarities:

- ⦿ Regulations
 - Numbered
- ⦿ Promise of quality insurance
- ⦿ Shaped by social and political reform
 - Tragedies
- ⦿ Continued improvement

General Differences:

- ⊙ Regulatory Enforcement
 - Recall
 - Letters of Action
- ⊙ Risk vs Benefit Information
- ⊙ Drug, Device Safety Assurance

Insights:

- ⊙ Tragedy occurrence
- ⊙ Medication Data Access
 - Medical Decisions
- ⊙ Medication Interactions
- ⊙ Drug Claims
 - Correct uses
- ⊙ Public safety
 - Toxicity
- ⊙ Self-maintainable system
 - Progress

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