Drug Educational Forum

Kansas City, Missouri

May 11, 2005

Disclaimer

- The information provided in this workshop does not take the place of the laws and regulations enforced by FDA
- Any reference to a commercial product, process, service or company is not an endorsement or recommendation by the U.S. government, HHS, FDA or any of its components

Disclaimer

- FDA is not responsible for the contents of any outside information referenced in this workshop
- This workshop does not convey any waiver of responsibility to the firm, nor impart any immunity to the firm for violations that may occur, even if you implement our recommendations as per 21 CFR 10.85(k)

No Smoking

Cell Phones, Pagers and PDA's

- Please make sure your cell phones, pagers and PDA's are set on "vibrate", "silent" or "off" mode.
- Please step outside if you must answer or make a call.

Protecting Consumers, Promoting Public Health

U.S. Food and Drug Administration


New
Product
Review
FDA

Agenda

- Drug Development
- Generic Drugs
- Over-The-Counter Drugs
- Chemistry, Manufacturing and Control
- 483's and Warning Letters
- Current Good Manufacturing Practices
- Financial Incentives
- The Small Business Representative

Science
Regulation
Consumer Protection

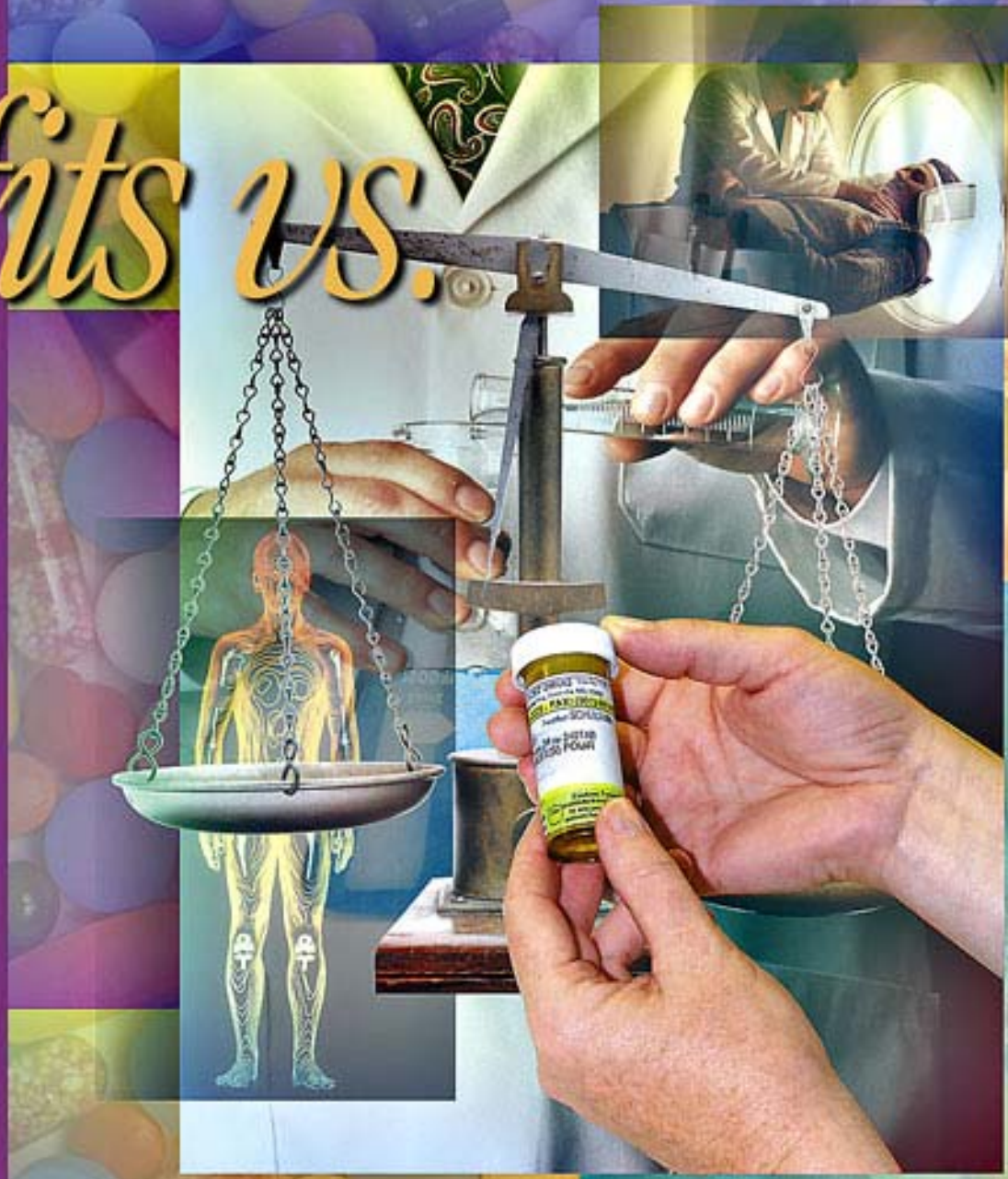
Medical Breakthroughs

FDA

Safe And Effective

FDA

Benefits vs. Risks



FDA

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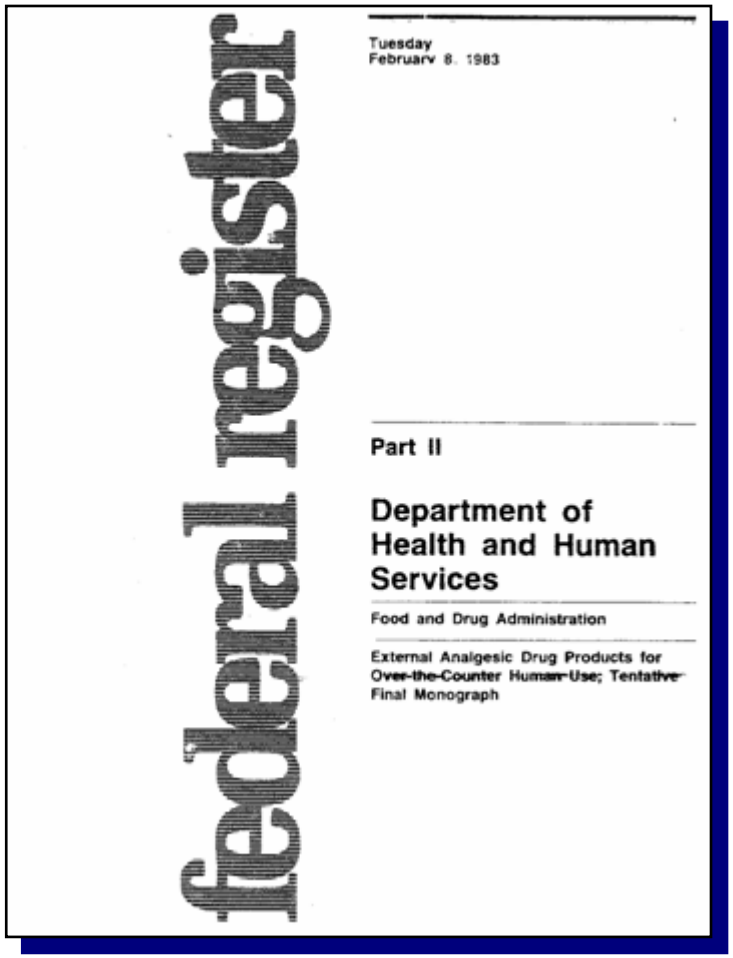
What are Laws?

- The basic enabling authority enacted by Congress
- Examples:
  - Federal Food, Drug and Cosmetic Act (FD&C)
  - FDA Modernization Act (FDAMA)
  - Prescription Drug User Fee Act (PDUFA)
  - Orphan Drug Act

What are Regulations?

- Implement the provisions of the law based on the authority provided by the law
- The development of regulations must follow specific procedures that allow public notice and comment
- Legally binding on industry and the agency

Federal Register


federal register

Tuesday
February 8, 1983

Part II

Department of Health and Human Services

Food and Drug Administration

External Analgesic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

- Official daily publication
  - Notices
  - Proposed Rules
  - Final Rules
- Free online through http://www.gpo.gov/ or http://www.fda.gov/
- GPO subscription

Code of Federal Regulations

- Title 21, Food and Drugs
- Published yearly
- Free online through
  - http://www.gpo.gov/
  - http://www.fda.gov/
- Order through GPO at 1-866-512-1800

Guidance Documents...

...Policy Statements and Advisory Opinions

- Serve to provide the Agency's interpretation of the law and applicable regulations
- The preamble to a regulation has the status of an advisory opinion
- Are not legally binding on the public or the agency

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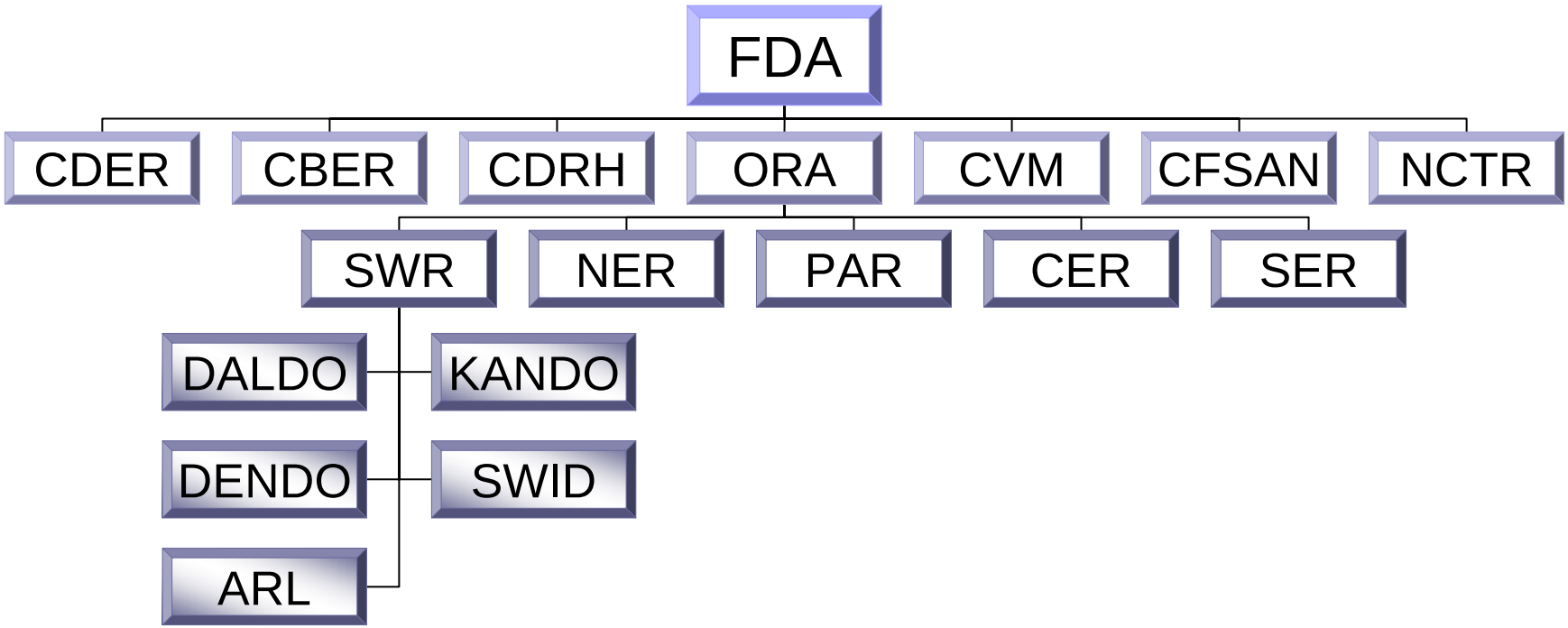
FDA In Your Neighborhood
FDA

Agency Organization



CDER

- Center for Drug Evaluation and Research
- Primary mission: to make certain that safe and effective drugs are available to the American people
  - Includes biological therapeutics

CBER

- Center for Biologics Evaluation and Research
- Regulates biological products
  - Blood and products derived from it
  - Vaccines
  - Human tissue for transplantation
  - Allergenic materials and anti-toxins

CDRH

- Center for Devices and Radiological Health
- Regulates firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States
- Regulates radiation emitting electronic products (medical and non-medical)

CVM

- Center for Veterinary Medicine
- Regulates the manufacture and distribution of food additives and drugs that will be given to animals

CFSAN

- Center for Food Safety and Applied Nutrition
- Ensures that the nation's food supply is safe, sanitary, wholesome, and honestly labeled
- Ensures that cosmetic products are safe and properly labeled

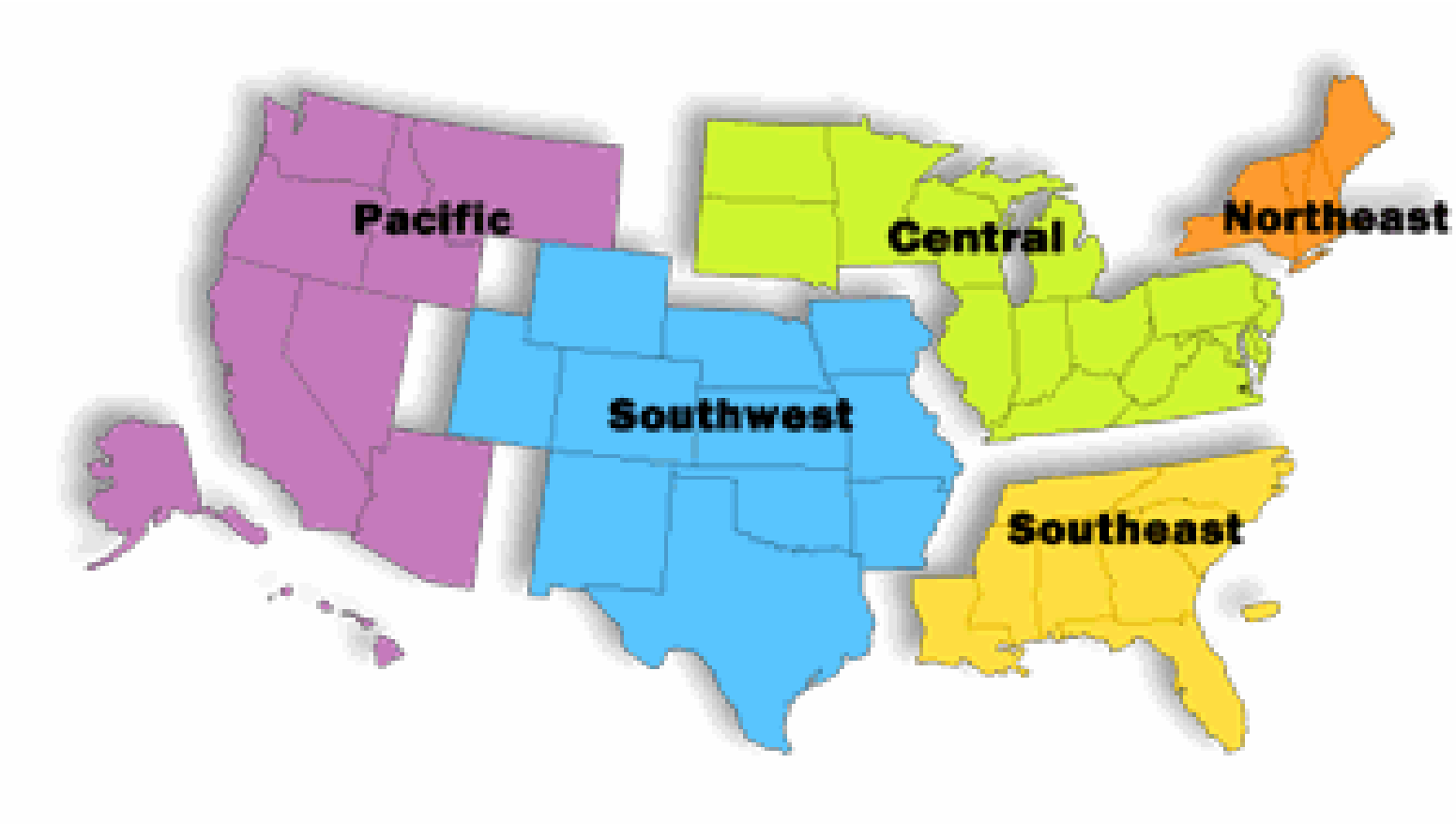
NCTR

- National Center for Toxicological Research
- Conducts peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs
- Fundamental and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by the FDA

ORA

- Office of Regulatory Affairs
- Lead office for all field activities of the FDA

FDA Regions



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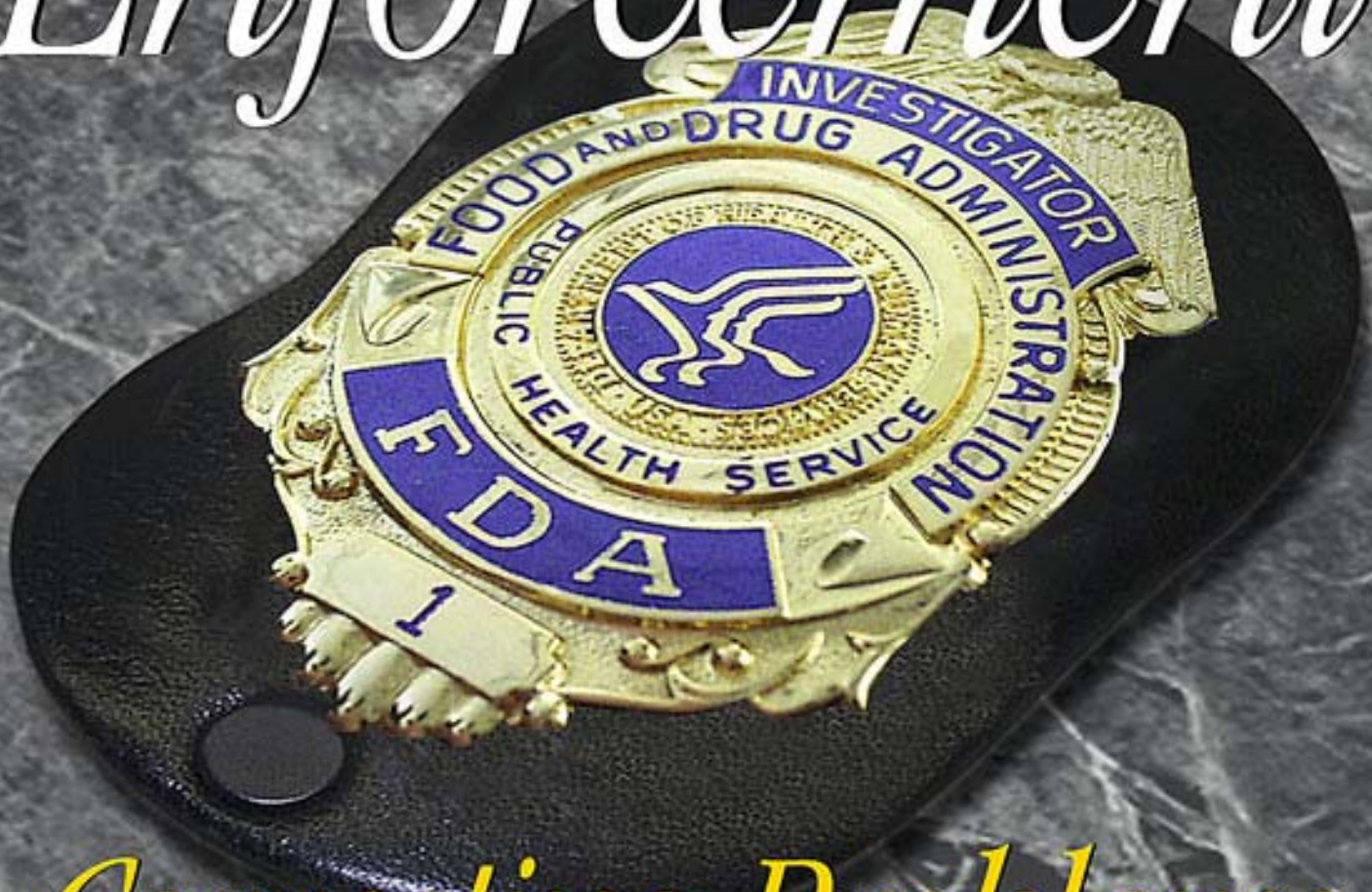
Enforcement



Correcting Problems

FDA

FDA Forms

- FDA 2656: Registration of Drug Establishment
- FDA 2657: Drug Product Listing
- FDA 2658: Registered Establishment's Report of Private Label Distributor
- FDA 482: Notice of Inspection
- FDA 483: Inspectional Observations

We Want You

To Voluntarily Comply!


U.S. Department of Health and Human Services
Food and Drug Administration
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Food
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Firm Will Stop Selling Laetrile. Christian Brothers Contracting Corp. has signed a consent decree agreeing to stop selling unapproved cancer therapy products commonly known as Laetrile, Vitamin B-17 or apricot kernels. Full Story
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