FDA's Radiation Regulatory Responsibilities

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The opinions I express today may not necessarily reflect the official position of the Food and Drug Administration (FDA) or the Department of Health and Human Services (DHHS). Similarly, the mention of any commercial products are neither an official endorsement or criticism of the product by me, the FDA, or DHHS.

Ground Rules

- Congressional Statutes define both NRC and FDA's responsibilities.
- Standards educate, define good practice.
  - Voluntary standards- Guidance, NUREG, Reports, Society publications, etc.
  - Regulations are Mandatory standards, requiring enforcement.
  - When is this warranted?

Food, Drug and Cosmetic Act (FDCA) - 1906

- Law has been amended more than 200 times.
- Laws* incorporated as subchapters within Title 21.
  - Subchapter D- Drugs (Part 300- original statute - 1906);
  - Subchapter F- Biologics (Part 600)
  - Subchapter H- Medical Devices (Part 800 - 1976)
  - Subchapter I - Mammography (Part 900 - 1992)
  - Subchapter J - Radiological Health (Part 1000-1968)

* These products associated with radiation

FDA Organization

- **Office of the Commissioner**
  - National Center for Toxicological Research
- **Office of Medical Products and Tobacco**
  - Center for Drug Evaluation and Research
  - Center for Biologics Evaluation and Research
  - Center for Devices and Radiological Health
  - Center for Tobacco
- **Office of Foods and Veterinary Medicine**
  - Center for Veterinary Medicine
  - Center for Food Safety and Nutrition
- **Office of Global Regulatory Operations and Policy**

Radiation Emitting Electronic Products (Radiation Control for Health and Safety Act of 1968)*

- Mandatory Emission Performance Standards
- Includes consumer and medical products
- Microwave ovens, lasers, cell telephones
- X-rays (medical and security products)

* Center for Devices and Radiological Health

Medical Device Act of 1976*

- 510 (k) – predicate device, substantial equivalency to preamendment devices
- Class I – Minimal controls
- Class II- Special controls
- Class III
  - High risk devices
  - May require clinical trials for premarket approval (PMA).
  - *Center for Devices and Radiological Health

What does it take to get a drug approved?

Human Subject Research under an Investigational New Drug (IND) Application

- Phase I- Safety “n ~ 20 – 80”
- Phase II- Efficacy “n < several hundred”
- Phase III- Large scale studies “n ~ several hundred to several thousand”

New Drug Application

- NDA Process:
  http://www.fda.gov/cder/regulatory/applications/nda.htm#Related%20Topics:

- Application Fee for NDA ~ $1 M^{+}

Manufacturing Inspection

New Drug manufacturing sites inspected prior to approval.

International manufacturing sites inspected by FDA staff.

FDA does not delegate it's regulatory authority to other agencies.

Any regulated product's manufacturing site is subject to FDA inspection.

Drug, biologic, or device?

Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

Y-90 Microspheres, tiny physically sealed sources (resin/glass) which are physically trapped in tiny hepatic blood vessels – classified as medical device.

Y-90 labeled monoclonal antibodies target CD20 antigen which were originally classified as biologic, now a therapeutic cancer drug. Mechanism of interaction is chemical.

My Regulatory Concerns

- Technologies are increasingly complex
- Statutory authorities are complex and do overlap
  NRC-FDA Memorandum of Understanding (MOU)
- Regulatory balance - General vs Prescriptive
- Education versus Regulation (Voluntary vs Mandatory)
- When does safety warrant a mandatory standard?

Acronyms

- CBER – Center for Biologics Evaluation and Research
- CDER – Center for Drug Evaluation and Research
- CDRH – Center for Devices and Radiologic Health
- DHHS – Department of Health and Human Services
- FDA – Food and Drug Administration
- FDCA – Food, Drug, and Cosmetic Act
- IND – Investigational New Drug
- NDA – New Drug Application
- NUREG – NRC technical report designation
- PMA – Pre-Market Approval

Thank You

Questions?

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