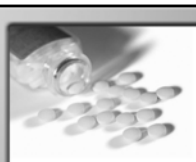
CDER Forum for International Regulatory Authorities

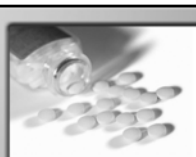
FDA CDER *Ombudsman*

CDER Ombudsman Activities

- *Discussion points*
  - *Ombudsman's role*
  - *Dispute resolution*
  - *Product jurisdiction*
    - *Combination products*
    - *Primary mode of action*



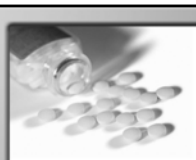
What is the Ombudsman??



The Ombudsman Is:

Someone in any organization who receives complaints, investigates and acts on them, who mediates disputes, and in general attends to problems involving interpersonal working relationships

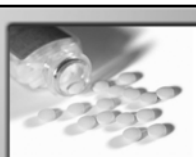
Dispute resolution



The Ombudsman Is:

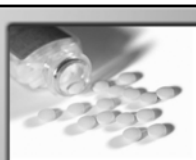
Dedicated to promoting and supporting

Fairness
Accountability
Equity



The Ombudsman's Goal is to:

Resolve disputes or disagreements

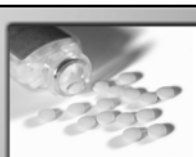


While Still

Maintaining **confidentiality**

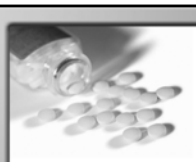
Maintaining **impartiality** as much as possible

Maintaining **independence**



Ombudsmen--Why do we need them??

Defuse issues and situations
Break stalemates
Unbiased sounding board and advice



FDA has Several Ombudsmen

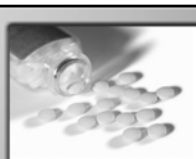
FDA

CDER

CBER

CDRH

CVM



Public Sector Ombudsmen

- Federal
- State
- Local (city, county)
- Universities

Dispute Resolution

Cited in FDA Law (FFDCA)

Cited in implementing regulations (21 CFR)

Explained in Guidances

Dispute Resolution

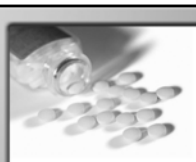
Code of Federal Regulations

10.75 Procedural Regulations

312.48 (INDs)

314.103 (NDAs)

Typically, delays in scheduling meetings, meeting minutes, timely replies, stalled IND development.

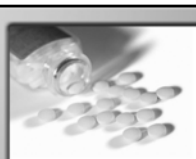


Dispute Resolution

312.48 (INDs) & 314.103 (NDAs)

Administrative and procedural issues

- 1st step is division PM and division management
- 2nd step is Center Ombudsman

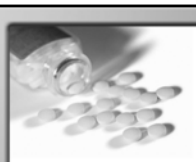


Dispute Resolution

312.48 (INDs) & 314.103 (NDAs)

Scientific and medical issues (generally formal disputes)

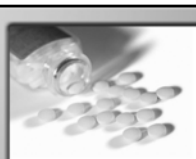
- Division, then Office, then Super Office, then Deputy Center Dir., then Center Dir.
- CDER Ombudsman may be contacted at any time in process



Dispute Resolution Codified in FDA Modernization Act

Section 404 provided for timely review of controversy

Amendment of 21 CFR 10.75 (Review of scientific controversy by appropriate advisory committee)



Dispute Resolution Explained in Guidances

Formal Dispute Resolution:
Appeals Above the Division Level
February 2000
(http://www.fda.gov/cder/guidance/2740fnl.htm)
30 day time clock

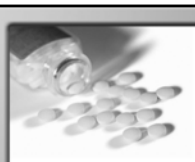
Dispute Resolution--Scientific Reviews

Documenting Differing Professional Opinions and Dispute Resolution--Pilot Program
MaPP 4151.2 11/04/04

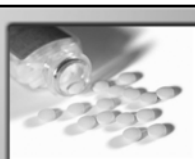
Provides for Ombudsman and Center Director review
Provides for ad hoc review panel

The CDER Ombudsman Also:

Receives **feedback** from inside and outside the Center about the effectiveness of programs and about problems that impede CDER's performance



INTERCENTER JURISDICTION



INTERCENTER JURISDICTION

FDA regulated products are:

Drugs

Biologics

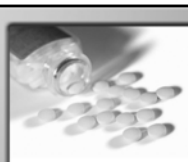
Devices

Cosmetics

Dietary supplements

Foods

Veterinary products



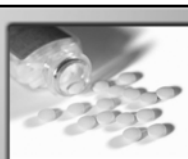
INTERCENTER JURISDICTION

So why does it matter which Center of FDA regulates my product?

$$$$$$ difference

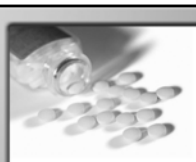
Evidence required for approval/clearance

Patent protection



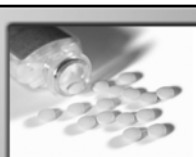
INTERCENTER JURISDICTION

- ***21 CFR 3.7 (Request for Determination)***
- ***FDA's Office of Combination Products***
- ***Affects drugs, devices, biologics***



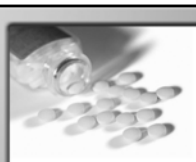
PMOA

- Drug Definition
  - Articles intended for use in the diagnosis, cure, mitigation, treatment, prevention of disease in man or animals, also
  - Articles intended to affect the structure or any function of the body of man or other animals



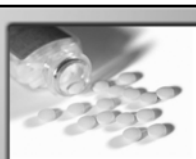
PMOA

- Device Definition
  - Articles intended for use in the diagnosis, cure, mitigation, treatment, prevention of disease in man or animals, also
  - Articles intended to affect the structure or any function of the body of man or other animals, AND



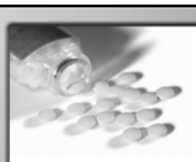
PMOA

- Device definition
  - …….. AND does not achieve its primary intended purposes through chemical action within or on the body of man and is not dependent upon being metabolized for the achievement of its primary intended purpose



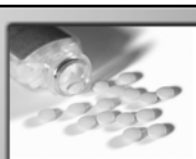
INTERCENTER JURISDICTION

- ***21 CFR 3.7 combination product is different from a 21 CFR 300.50 combination product***



INTERCENTER JURISDICTION

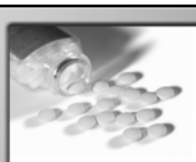
- ***A 21 CFR 300.50 combination product is a drug-drug combination (totally different from a 3.7 combination)***
  - ***i.e., atenolol/HCTZ***



INTERCENTER JURISDICTION

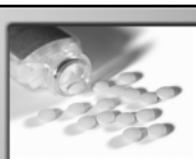
21 CFR 3.7 combination product is a

- ***Drug-device***
- ***Drug-biologic***
- ***Biologic-device, etc.***



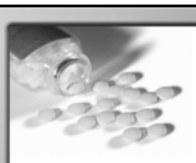
INTERCENTER JURISDICTION

- ***…but there are no cosmetic or food combination products in the statutes***



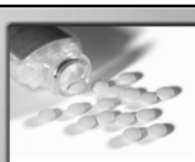
INTERCENTER JURISDICTION

- **Combination products are not devices, drugs or biologics – they are a separate entity**
- **Regardless of which Center has lead, the same safety and effectiveness questions need to be addressed**



INTERCENTER JURISDICTION

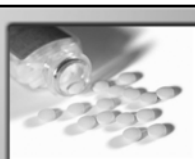
- http://www.fda.gov/oc/combination/



INTERCENTER JURISDICTION

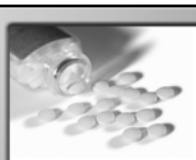
Combination products examples:

- **Convenience kit or co-package (surgical tray)**
- **Drug/biologic coated device (drug coated stent, antibiotic wound dressing, artificial hip joint with antibiotic)**
- **Prefilled drug/biologic delivery system (syringe, patch, Vitrasert)**
- **Drug/biologic (Rebitrol/ribavirin)**
- **Laser activated drug (Visudyne)**



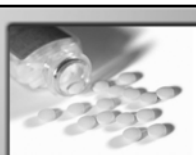
INTERCENTER JURISDICTION

- Medical Device User Fee and Modernization Act (2002) -- provides for single application to review combination products



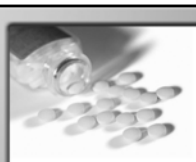
INTERCENTER JURISDICTION

- Example of mixing authorities-- bone void filler with tobramycin (CDRH lead)
  - Manufacturing 21 CFR 820
  - AR reporting 803
  - GMP for drugs for T (501 of Act)
  - Clinical invest. IDE (812)
  - Consultative review



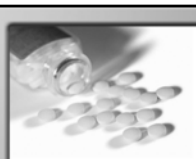
Intercenter Jurisdiction

- Combination Products
  - Primary Mode of Action (PMOA) determines lead Center
  - PMOA--"the means by which a product achieves a therapeutic effect."



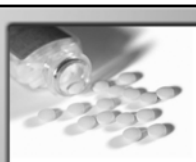
Intercenter Jurisdiction

- Center assignment determined by combination component with primary intended purpose
- If it is not apparent which component has the primary effect, then we use a 2-tiered algorithm



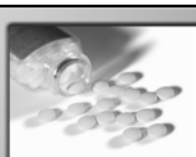
Intercenter Jurisdiction

- 1st--assign to Center with similar questions of S&E (consistency),
- 2nd--assign to Center with the most expertise to evaluate the most significant S&E questions



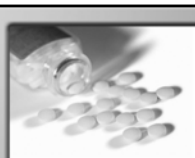
PMOA

- Public examples of designation "1-liners"



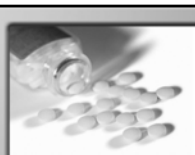
PMOA--CDRH Lead

- Catheter lock flush solution with antimicrobial and anticoagulant agents
- Bone void filler with antibiotic
- Adhesive bandage with antibiotic
- Drug-eluting cardiovascular stent to reduce restenosis



PMOA--CDER Lead

- Photosensitizing drug and light source for cancer treatment
- Chemical agent and delivery system for gallstone
- Chlorhexidine gluconate swabs
- Fluoride-containing dental device for anticaries treatment



Your Center contact for disputes, jurisdictional issues, industry and consumer complaints--

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