Challenges of Regulating Combination Products

Consensus Summit:
Combination Product Regulatory Issues
RAPS – January 11, 2005

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Combination Products Are Diverse

All combine different types of products:

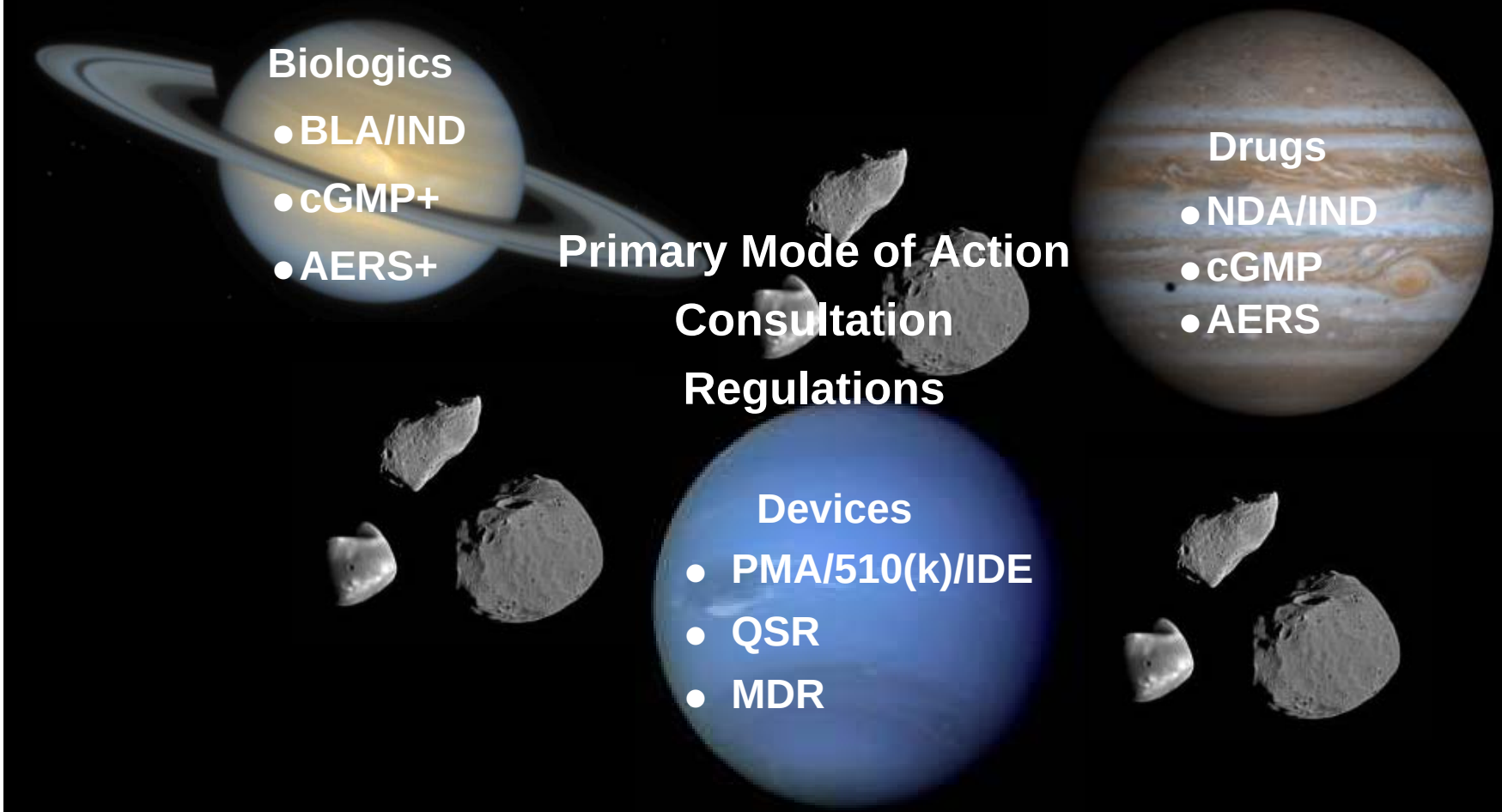
- Drug-device
- Device-biologic
- Drug-biologic
- Drug-device-biologic

Combination Products Are Diverse

They can be:

- Physically or chemically combined
- Co-packaged in a kit
- Separate, cross-labeled products

Regulatory Approaches Are Diverse



Challenges: Overall Regulation

No regulatory scheme designed specifically for combination products….

No marketing application designed for combination products…..

…..We work within existing statutory framework.

Challenges: Overall Regulation

FDA regulations/practices differ for drugs and devices

- GMP's vs. QSR's
- adverse event reporting
- labeling
- premarket applications
- promotion and advertising
- user fees

Industries differ

- different experience and preferences

The Ultimate Regulatory Challenge

Making regulation

- **clear**
- **consistent**
- **predictable**
- **appropriate**

without raising the bar…..

Challenges: Assignment

Define **primary mode of action**….

And then apply it….

….Some products don't have a clearly identifiable PMOA

Challenges: Assignment

60-day RFD clock sometimes tight

- complex issues
- binding decisions

Challenges: Assignment

RFD's are voluntary …

we don't see all products for assignment

Transparency …

more difficult to achieve than we'd like

Challenges: Assignment

Sponsors' preferences don't always square with what the law requires

Challenges: Review

No application specifically for combination products …

- standard submission format and content must be tailored

Regulatory pathways sometimes not evident…

- e.g., need for cross labeling

Challenges: Review

Two centers involved – they have different:

- review time frames
- clinical trial perspectives
- user fees
- submission tracking systems
- locations
- cultures

Challenges: Review

The volume!

Over **200** cross center collaborations for combination products in FY 2004.

Other Challenges

- OCP budget and staff size
- Ongoing education and outreach to sponsors and review staff
- Combination product issues over complete regulatory life cycle
- One size doesn’t fit all

The Future is Bright!

- Numbers and types of combination products continue to grow
- Consultation process more systematized
- Clearer, more predictable process for assignment, premarket review and postmarket regulation
- Continued opportunities for stakeholder input at meetings like this!