Office of Combination Products: Roles and Progress

Consensus Summit:
Combination Product Regulatory Issues
RAPS – January 12, 2005

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Overview

- What do we do?
- How do we do it?
- What have we done so far?
- What's next…..

What do we do?

- Make jurisdictional determinations
- Oversee premarket review
- Oversee postmarket regulation
- Resolve disputes
- Develop policy, guidance and regulations
- Serve as resource for industry and review staff
- Outreach
- Report to Congress
- Special Initiatives

Jurisdictional Determinations

Formal

Or

Informal

We strive for transparency

How do we do it?

- Requests for Designation – 67 last year

  100% on time !!

- Informal Decisions for many products – phone, email, pre-RFD's
- Primary Mode of Action Rule
- Jurisdictional Updates
- Published ~70 Jurisdictional Determinations
- Resolve appeals of TRG determinations
- Monthly Meetings with Jurisdictional Officers

Jurisdictional Determinations

What's Next….

- **Finalize PMOA rule**
- **Define chemical action**
- **Publish more jurisdictional updates**
- **Publish more jurisdictional determinations**
- **Intercenter Agreements**
- **…and more**

Premarket Review

Whatever it takes to ensure

“timely

and effective”

premarket review of combination products

How do we do it?

- SOP for intercenter consultation process
- Establish and clarify regulatory pathways
- Establish and facilitate intercenter working groups and internal MOU's
- Facilitate meetings with sponsors
- Monitor and facilitate the consultation process (> 200 in FY04)

How do we do it, more

- Monitor combination product review timeliness
- Advise sponsors and review staff
- Provide training and reviewer tools
- Check classification of all submissions as combination products

Premarket Review

What's Next…

- One Application or Two
- Automated Consultation Tracking System
- Cross Labeling
- Post Approval Changes
- Labeling Format & Content
- Submission Format & Content
- …and more

Postmarket Regulation

Ensure

“consistent and

appropriate”

postmarket regulation

How do we do it?

- GMP Guidance
- Identify appropriate regulatory mechanisms
- Coordinate Centers and Field Offices

Postmarket Regulation

What's Next…

- Adverse Event Reporting Guidance
- Promotion & Advertising
- Registration & Listing
- …and more

Dispute Resolution

Facilitate resolution of …

- disputes about the timeliness of premarket review of combination products
- other disputes or disagreements

How do we do it?

- Dispute Resolution Guidance
- Meetings
- Phone Calls
- Email

Dispute Resolution

What's Next…

- Final Dispute Resolution Guidance

Policy, Guidance, and Regulations

Review and update

- guidances
- agreements
- practices

Issue

- guidances
- regulations

How do we do it?

- PMOA rule –definition and assignment algorithm
- Jurisdictional Updates
- Jurisdictional Determinations
- Guidance: User Fees, GMP's, Dispute Resolution

  GGP Process – draft, comments, final
- Meetings: internal and external stakeholders

Policy, Guidance, and Regulations

What's Next…

- Finalize PMOA Rule
- One Application or Two
- Adverse Event Reporting
- Cross Labeling
- Chemical Action
- More jurisdictional updates
- More jurisdictional determinations
- Intercenter Agreements
- …and more

Resource for Industry and Review Staff

Wide range of inquiries on

assignment

and

combination product

regulation

How do we do it?

- Phone
- Email
- Meetings
- Web
- FAQ

Resource for Industry and Review Staff

What's Next…

keep going!

Outreach

Training

and

Outreach

How do we do it?

- Presentations
- Courses (e.g., Introduction to CDER for CDRH Reviewers)
- Web
- Public Meetings

Outreach

What's Next…

Activities already planned for **2005!!**

Report to Congress

Annual Report

- Activities and Impacts
- Data on
  - Assignment
  - Receipt of Marketing Applications
  - Review of Marketing Applications

How do we do it?

- OCP Activities Tracking
- Combination Product Categorization
- Monthly Monitoring of Center activities
- Reports Posted on FDA Website

Report to Congress

What's Next…

FY04 Report coming soon!

Special Initiatives

- Pharmacogenomics
- Novel Drug Delivery
- Tissue Engineering

How do we do it?

Member of

- pharmacogenomics working group
- novel drug delivery working group

Meetings with

- tissue engineering community

Special Initiatives

What's Next…

- Guidance document on pharmacogenomic Dx/Tx co-development
- Guidance document on novel drug delivery systems
- CBER-CDRH joint review team for tissue engineered medical products

Anything Else?

- Evaluate impact of new policies on combination products
- Continued stakeholder input, outreach and training

…and more

OCP Website:

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

FDA U.S. Food and Drug Administration — Department of Health and Human Services

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Office of Combination Products

Overview of the Office of Combination Products

Definition of a Combination Product

Product Jurisdiction/Assignment of Combination Products:

Definition of the Primary Mode of Action of a Combination Product [PDF 63KB] -- Comment Period Extended [PDF 96KB]

Combination Products Primary Mode of Action (PMOA) Proposed Rule: May 7, 2004, Federal Register - Presentation

- Instructions for Submitting a Request for Designation (RFD)
- Assignment of Combination Products/Product Jurisdiction Program - Final Rule *(June 23, 2003)*
- Jurisdictional Updates
  - Jurisdictional Determinations
  - Drug-Biologic Combination Products
  - Human Demineralized Bone Matrix
  - Drug-Eluting Cardiovascular Stents
  - Dental Prophylaxis Pastes with Drug Components
- Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research
- Intercenter Agreements
- FY04 OCP Review Performance: Formal Requests for Designation Submitted by Industry - Updated *(October 1, 2003 – September 30, 2004)*

Guidance Documents and Procedures

- Draft Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products [PDF 302KB] *(September 2004)*
- Draft Guidance for Industry and FDA Staff: Application User Fees for Combination Products [PDF 1.33MB] *(September 2004)*
- Draft Guidance for Industry: Combination Products, Timeliness of Premarket Reviews: Dispute Resolution Guidance [PDF 28KB]
- Selected Guidance Documents Applicable to Combination Products.
- Intercenter Consultative/Collaborative Review Process [PDF 82KB] HTML

Reports, Workshops and Presentation

- Recent OCP Presentations
- Recent Article in Medical Device & Diagnostic Industry Magazine: Forging New Regulatory Pathways at FDA
- Office of Combination Products: Annual Report to Congress[PDF 251KB] HTML
- Progress Reports to Stakeholders
- Innovative Systems for Delivery of Drugs and Biologics: Scientific, Clinical and Regulatory Challenges: Summary of FDA Workshop *(July 8, 2003)*
- November 25, 2002 Public Hearing on Regulation of Combination Products
  - Federal Register Notice
  - Agenda and Presentations
  - Transcript of Nov. 25, 2002 Public Hearing -[PDF 213KB] HTML
- Regulation of Combination Products: FDA Employee Perspectives [PDF 74KB] [HTML]

What's New

- **NEW!** Recent OCP Presentations
- **NEW!** Recent Article in Medical Device & Diagnostic Industry Magazine: Forging New Regulatory Pathways at FDA
- Updated FY04 OCP Review Performance: Formal Requests for Designation Submitted by Industry
- **NEW!** Draft Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products [PDF 302KB] *(September 2004)*
- **NEW!** Jurisdictional Determinations
- **NEW!** Draft Guidance for Industry and FDA Staff: Application User Fees for Combination Products [PDF 1.33MB] *(September 2004)*
- Recent Examples of Combination Product Approvals
- FDA Proposes Rule on "Combination" Products *(May 6, 2004)*

Contact Us

We are interested in your comments and suggestions about combination products issues. Please contact:

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