Combination Products Update

Xavier Health Combination Products Summit 2016
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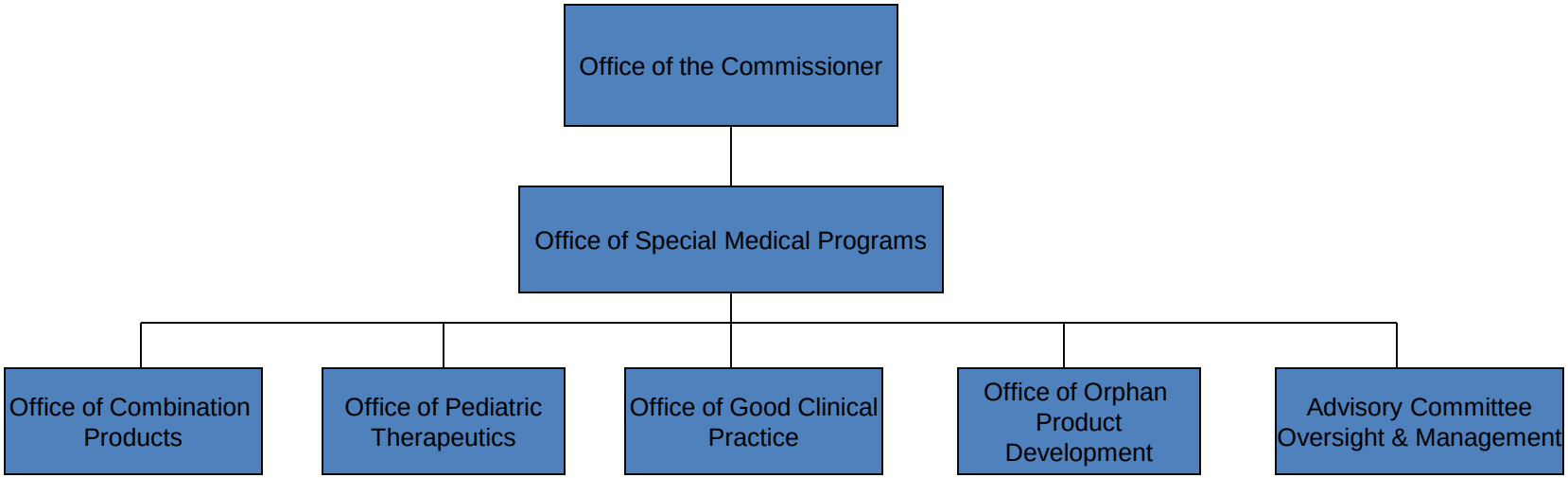
Office of Combination Products
U.S. Food and Drug Administration

Where is OCP?


Office of the Commissioner
Office of Special Medical Programs
Office of Combination Products
Office of Pediatric Therapeutics
Office of Good Clinical Practice
Office of Orphan Product Development
Advisory Committee Oversight & Management

Who's in OCP?

Currently, we are a staff of 12:

3 Scientists: Jose Moreno, Joe Milone, Diana Yoon

3 Physicians: Patricia Love, Bindi Nikhar, Maryam Mokhtarzadeh

2 Attorneys: John Weiner and Leigh Hayes

2 Engineers: Thinh Nguyen and Melissa Burns

1 IT Specialist: Danita Dixon

1 Administrative Assistant: Bibi Jakrali

Centers' Representatives

- CDER: Kristina Lauritsen and Cherryn Chang
- CDRH: Angela Krueger, James Bertram, Andrew Yeatts (on detail)
- CBER: Sherry Lard and Richard McFarland
- OCC Combination Product Team

Overview

- Combination Products Policy Council
- Pre-Request for Designation (Pre-RFD)
- Combination Products Intercenter Consult Request (ICCR) Pilot Process

Combination Products Policy Council

- FDA established the Combination Products Policy Council in Spring 2016

- The Council is chaired by the Deputy Commissioner for the Office of Medical Products and Tobacco (OMPT)

Combination Products Policy Council

Center/Office	Participants
Center for Biologicals Evaluation and Research (CBER)	• Center Director or designee • Center representative
Center for Drug Evaluation and Research (CDER)	• Center Director or designee • Center representative
Center for Devices and Radiological Health (CDRH)	• Center Director or designee • Center representative
Office of Combination Products	• Office Director or designee
Office of Special Medical Programs	• Associate Commissioner or designee

Council Purpose

- Provides leadership oversight to a senior-level forum to establish combination product policy across FDA

- The Council has decisional authority:
  - Ensure consistency in required evidentiary standards and data requirements for marketing
  - Evaluate and update cross-cutting existing policy to assure the safety, efficacy, and availability of products
  - Develop and implement new cross-cutting policy to promote development of innovative products

Council Purpose (cont.)

- Addresses regulatory and scientific policy issues and a forum for developing guiding principles related to combination products, cross-labeled products, and medical product classification
- Resolves disagreements among Centers, OCP, and/or sponsors on activities and policies related to these topics
- The Council is a platform for intercenter collaboration that results in coordinated and consistent policy across the Agency with regards to combination products
- The Council will continue to promote cross-Agency collaboration as issues arise in the future

Communicate with the Council

- Should you have questions about the Council:
  - CombinationProductCouncil@fda.hhs.gov
- For updates regarding the Council, visit:
  - http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm519751.htm

Pre-RFD

- May be helpful during early stage of product development
- Similar to the formal RFD process
- Preliminary product classification assessment
- Goal is to respond to sponsor within 60 days from receipt of complete information
- Communicate with sponsors as needed during the review
- Draft guidance is under development

ICCR - Where We Were

- SMG 4101 (2004) “Combination Products Intercenter Consultative/Collaborative Review Process”
  - Email based process
  - Timelines established on consult-by-consult basis (non-standardized deadlines)
  - No comprehensive system to identify who/ when/how to contact another Center for consult
  - No automated system for tracking intercenter consults

ICCR- What's Been Happening

- Increasing collaboration by FDA staff on the review of combination products
- Increasingly complex products requiring cross-Center expertise
- Increase in number of performance goals
- Reorganizations in the Centers
- Increase in number of intercenter consult requests

What We Did

- FDA's Office of Planning conducted an independent assessment on the intercenter consult process and provided recommendations

- Solicited input from regulated industry and review staff from CBER, CDER, and CDRH

What Problems Were Identified

- Coordination:
  - Different policies, practices and application types
  - Separate review and tracking systems for each center
  - Challenges accessing other centers' IT systems
- Communication:
  - Uncertainty regarding consult procedures
  - Difficulty identifying combination product contacts
  - Lack of clarity on purpose for information requests
- Resources:
  - Limited resources to review consults

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Recommendations

- Establish clear guidance for the review of common combination product types
- Simplify processes for access to databases for combination product reviewers
- Improve intercenter review process and associated SOPs
- Maintain a current FDA-internal list of combination product contacts throughout Centers and OCP

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http://www.fda.gov/downloads/CombinationProducts/GuidanceRegulatoryInformation/UCM467128.pdf

Perhaps the easiest way to find out…Contact Us!

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http://www.fda.gov/CombinationProducts/default.htm

Contact Us!

- **301-796-8930**

- **combination@fda.gov**