



AdvaMed

Advanced Medical Technology Association

Combination Products: Regulations, Guidances, Proposed Rules, Strategies, and Practical Challenges

Washington, DC
November 16 – 17, 2009

Monday, November 16

8:30 – 9:00

Breakfast

9:00 – 9:05

Welcome: Thomas Maeder, Executive Director, MTLI, AdvaMed
Khatereh Calleja, Assoc. Vice President, Technology &
Regulatory Affairs, AdvaMed

9:05 – 9:30

Combination Products: Past, Present, and Future

Janet Trunzo, Executive Vice President, Technology and Regulatory Affairs, AdvaMed

- Historical background
- Definitions and regulatory authority
- Examples and challenges
- Future directions

9:30 – 10:30

Primary Mode of Action (PMOA) and Request for Designation (RFD)

Thinh Nguyen, Director, Office of Combination Products, FDA

- What is the PMOA and how is it determined?
- The request for designation (RFD) and how the process works
- The FDA decision-making process
- Pitfalls, challenges, and examples

10:30 – 10:45

Break

10:45 – 12:00 PMA, 510(k)s, 513(g)s, and Combination Products

Christy Foreman, Deputy Director for Engineering and Science Review, CDRH

- Differences between PMA and 510(k) processes
- 513(g) and RFD
- What difference does the submission route for one component have on the regulatory requirements for the other?
- Best practices for combination products requiring a PMA
- Meetings with OCP and Centers to discuss combination products

12:00 – 1:15

Lunch

1:15 – 2:00 Comprehensive Development Strategies with Case Studies

Alberto Velez, Director, Quality and Compliance Worldwide, Johnson & Johnson

- Practical and logistical challenges of coordinating combination product development between different companies or business units
- Establishing early, productive communication and timelines to facilitate efficient, effective submissions

2:00 – 2:45

Labeling and Cross-labeling of Combination Products

Suzanne O'Shea, Counsel, Baker & Daniels, former Product Classification Officer, Office of Combination Products, FDA

- What are the challenges of labeling integrated products?
- How do you determine which aspects of labeling to include?
- What are the relationships between the two manufacturers in a cross-labeled product?
- What are your options if the other manufacturer does not wish to cooperate?
- Strategies and case studies

2:45 – 3:00

Break

3:00 – 4:30 Proposed Rule on cGMPs for Combination Products – Presentations and Discussion

John Barr Weiner, Associate Director for Policy and Product Classification Officer, Office of Combination Products, FDA

Jim Cohen, Partner, Buchanan Ingersoll & Rooney, formerly with the Office of Combination Products, FDA

Winifred Wu, Vice President, Regulatory Affairs, Medtronic

- Historical context on combination product cGMPS
- The proposed rule on cGMPs for combination products
- How is the current system likely to change?
- Practical implications, issues, and concerns

- Moderated discussion

4:30 – 5:00 **Panel Discussion**
Moderator: Winifred Wu, Vice President, Regulatory Affairs, Medtronic

5:00 **Reception**

Tuesday, November 17

8:00 – 8:30 **Breakfast**

8:30 – 9:45 **Adverse Event Reporting and the Proposed Rule**
Leighton Hansel, Director, Regulatory Affairs, Abbott Laboratories

- Current and interim AE reporting procedures and issues
- The proposed rule on postmarket safety reporting for combination products
- Issues and industry concerns

9:45 – 10:30 **Pre- and Post-Approval Inspections of Combination Products**
Anastacia Bilek, Branch Chief, OPMD Division of Enforcement, FDA

- What are the issues and challenges of combination product inspections?
- Organization and coordination between Centers and the District

10:30 – 10:45 **Break**

10:45 – 11:30 **Post-Approval Changes**
Phoebe Mounts, Partner, FDA/Healthcare Regulation Practice, Morgan Lewis

- Post-approval manufacturing changes
- Change reports for drugs, biologics, and devices
- Addressing post-approval changes for cross-labeled devices

11:30 – 12:00 **Closing Discussion**
All Faculty

12:00 **Adjournment**

