



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Combination Products Regulation in the United States

2012 AHC-AHWP Joint Workshop
on Medical Device Combination Products
November 4, 2012
Taiepei, Taiwan

John Barlow Weiner, Esq.
Associate Director for Policy
Office of Combination Products
US Food and Drug Administration



Plan

- Brief overview
- Topics of potential interest



Overview

- Timeline
- Definition
- Primary mode of action (PMOA)
- Premarket approach
- Postmarket approach



Topics of potential interest

- Distinct product class
- Application/reconciliation of requirements
- Coordination
- Convergence
- Role of Office of Combination Products



Thank You

Additional information

OCP website: <http://www.fda.gov/CombinationProducts/default.htm>

Contacting OCP:

- combination@fda.gov
- 1-301-796-8930
- john.weiner@fda.hhs.gov
- Office of Combination Products
Food and Drug Administration
15800 Crabbs Branch Way (HFG-3)
Suite 200
Rockville, MD 20855