# Regulation of Combination Products

Workshop on Innovative
Administration Systems for Vaccines
December 18-19, 2003

Mark D. Kramer
Director, Office of Combination Products

# Combination Products

- Handout provides variety of information relevant to regulation of combination products
  - What is/is not a combination product
  - Regulation of combination products
  - Role of Office of Combination Products
  - Assignment of combination products
  - Premarket review of combination products
  - Postmarket regulation of combination products
  - OCP website
  - Contact information

# Vaccine Delivery

- Definition of Combination Product (21 CFR 3.2(e)):
  - Drug-device, drug-biologic and biologic-device products are combination products (see handout for details)
  - Vaccines incorporating delivery devices (including transdermal patches, jet injectors and syringes) are biologic-device combination products

# Regulation of Combination Products

- Assigned to lead Center based on "primary mode of action"
  - Role of biological component vs. delivery vehicle
- Intercenter consultation/collaboration
- One application vs. two
- Premarket regulatory authorities
- Postmarket regulatory authorities

# Review of Combination Products

- Not starting from scratch – significant agency experience in dealing with alternative methods of drug delivery that can be applied to vaccine products
- Intercenter Consultation Process
  - www.fda.gov/oc/ombudsman/intercentersop.pdf
  - OCP role in monitoring intercenter consultations
- OCP and Centers encourage sponsors to consult with agency early during development of novel products; involve CBER and CDRH if appropriate

# How Does the Future Look?

- Numbers and types of combination products will continue to grow
- Consultation process more systematized
- Clearer, more predictable process for assignment, premarket review and postmarket regulation