M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: March 9, 2001 ,

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Role of Medical Officer in OGD

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Role of Medical Officer in OGD

Presented for: OGD Orientation

Date Presented: March 9, 2001

Presented by: Mary M. Fanning, M.D.Ph.D.
Associate Director for Medical Affairs

Number of Pages: 16

Melissa Lamb

Attachment

90S-0308

M709

ROLE OF MEDICAL OFFICER IN OGD

February 9, 2001

Mary M. Fanning, M.D.Ph.D.
Associate Director for Medical Affairs

REVIEW

- Bioequivalence studies with clinical endpoints
  - Drug products that are not systemically absorbed
    - topical drug products
    - vaginal drug products
    - nasal drug products
    - inhaled steroid drug products

REVIEW

- Bioequivalence studies with clinical endpoints
  - Drug products with special safety concerns
    - transdermal drug products
      - skin irritation studies
      - skin sensitization studies

REVIEW

- Protocols for Bioequivalence studies with Clinical endpoints
  - Work closely with ORM review divisions to maintain consistency in study endpoints and design

GUIDANCE DEVELOPEMENT

- Completed - Skin Irritation Sensitization Studies (For transdermals)
- In Draft - Topical Antifungal, Vaginal Antifungal and Ance Drug Products
- Ongoing - Nasal Steriod Drug Products Dermatopharmacoknetics (DPK)

CONTROLLED CORRESPONDENCE

- Clinical Study Design Questions
- Safety Issues

SAFETY EVALUATIONS

- Health Hazard Evaluations (HHE)
- Post-Marketing Issues
- Product Quality Reports
- Adverse Event Reports

HEALTH HAZARD EVALUATIONS

Should they be recalled?

- Are there adverse event reports?
- Is there an at risk population?
- What is the potential "hazard"?

HEALTH HAZARD EVALUATIONS

Should they be recalled?

- Degree of Seriousness?
  - Life-threatening
  - Severe
  - Moderate
  - Limited
  - None
- Likelihood of Occurrence?
- Immediate or Long-range consequences?

HEALTH HAZARD EVALUATIONS

How Extensive Should the Recall Be?

- Class I - Has a reasonable probability of causing serious adverse health consequences or death.
  Recall to the consumer level.
- Class II - May cause temporary or medically reversible or remote serious adverse health consequences.
  Recall to the pharmacy level
- Class III - Is not likely to cause adverse health consequences.
  Recall to distribution level.

SAFETY EVALUATIONS

- Adverse Event Reports
- Inactive Ingredients

COMMITTEES

- TIACC - Therapeutic Inequivalence Action Coordination Committee
- Pediatrics
  - PDIT - Pediatrics Implementation Team
  - Pediatric Exclusivity Board
- Suitability Petitions Committee

COMMITTEES

- Topical Drug Products Working Group (Dermatological drug products)
- Oral Inhalation and Nasal Drug Products
  - Clinical endpoints working group-Oral inhalation & nasal drug products
  - Safety (impurities) working group-Oral inhalation & nasal drug products
  - Categorical endpoint analysis working group

COMMITTEES

- Risk Management Committee
- Research Coordinating Committee (RCC)
  - representing Regulatory Science & Review Enhancement
- Regulatory Science and Review Enhancement (RSR) subcommittee of RCC, Chair

ADDITIONAL TASKS

- Microbiology Supervisor
  - work with microbiology team to ensure quality review of sterility assurance for sterile drug products

REVIEW SCIENCE AND REGULATORY ENHANCEMENT INITIATIVE

- Coordinate peer review process of annual competition
- Monitor progress of projects