

M E M O R A N D U M

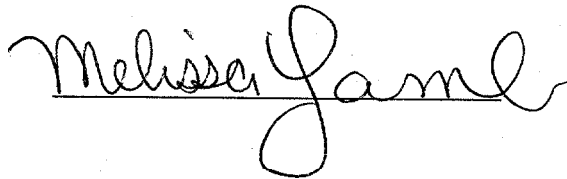
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

~~2096 '01 MAR 12 12 47~~

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



Attachment

905-0308

M 709

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
 - 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