

M E M O R A N D U M

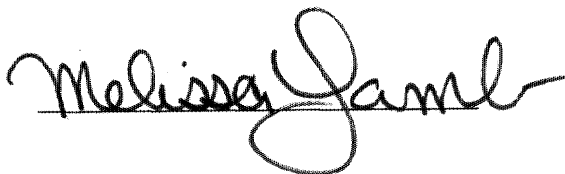
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

5129 '01 NOV 30 P1:52

Date: November 27, 2001  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: Pediatric Exclusivity Overview

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: Pediatric Exclusivity Overview  
Presented for: 2001 Fall Technical Workshop  
Date Presented: October 29, 2001  
Presented by: Mary Fanning M.D., Ph.D.  
Associate Director for Medical Affairs  
Office of Generic Drugs  
Number of Pages: 12



Attachment

90S-0308

M 721

# PEDIATRIC EXCLUSIVITY OVERVIEW

2001 FALL TECHNICAL WORKSHOP  
OCTOBER 29, 2001



Mary Fanning, M.D., Ph.D.  
Associate Director for Medical Affairs  
Office of Generic Drugs

ACCESSING INFORMATION

WRITTEN REQUEST PROCESS

PEDIATRIC EXCLUSIVITY

BOARD DETERMINATIONS

# ACCESSING INFORMATION

☛ [Http://www.fda.gov/cder/pediatric/index.htm](http://www.fda.gov/cder/pediatric/index.htm)

# ACCESSING INFORMATION

## ☛ Written Requests Issued

- As of 10/1/01 - 202

## ☛ Written Requests Issued by Approved Active Moieties

# WRITTEN REQUEST PROCESS

## • Identify drug product (moiety)

- List of products for which additional pediatric information may provide a health benefit for children
  - CDER, Professional Groups
  - Future - FDA & NIH

# WRITTEN REQUEST PROCESS

## • Draft WR

- Division and/or Sponsor Initiated
- Template - issues to address
- Template for drug product groups
- PdIT Review - guidance and consistency

# PEDIATRIC EXCLUSIVITY BOARD DETERMINATIONS

## • Pediatric Exclusivity Granted

- 42 active moieties
- 4 simultaneous approvals, adult and pediatric

## • Pediatric Exclusivity Denied

- 7 active moieties
- Did not meet terms of the written request



# PEDIATRIC EXCLUSIVITY BOARD DETERMINATIONS

- “Met” versus “Fairly Met” terms of  
Written Request
- Intent of Studies

# PEDIATRIC EXCLUSIVITY BOARD DETERMINATIONS

## • ACCESSING INFORMATION

- Pediatric Exclusivity Granted
  - Posted on website

# PEDIATRIC EXCLUSIVITY

## Labeling Changes - 20

- Safety and/or Efficacy - label to a lower age
- Dose and dose adjustments for selected age groups
- New indication in children
- AEs in specific subgroups
- AEs related to developmental process in children
- Safety and Efficacy NOT established in children

# FUTURE

- NIH participation
- Aim for labeling to neonatal age groups
- Labeling linked to exclusivity