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: 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

Melissa Lamb

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

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