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

Date: March 6, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: National Association of Pharmaceutical Manufacturers

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: Update from the Office of Generic Drugs

Presented for: Mid-Year Meeting

Date Presented: May 15, 2000

Presented by: Robert L. West, M.S. R. Ph.

Number of Pages: 8

Melissa Lamb

Attachment

90S-0308

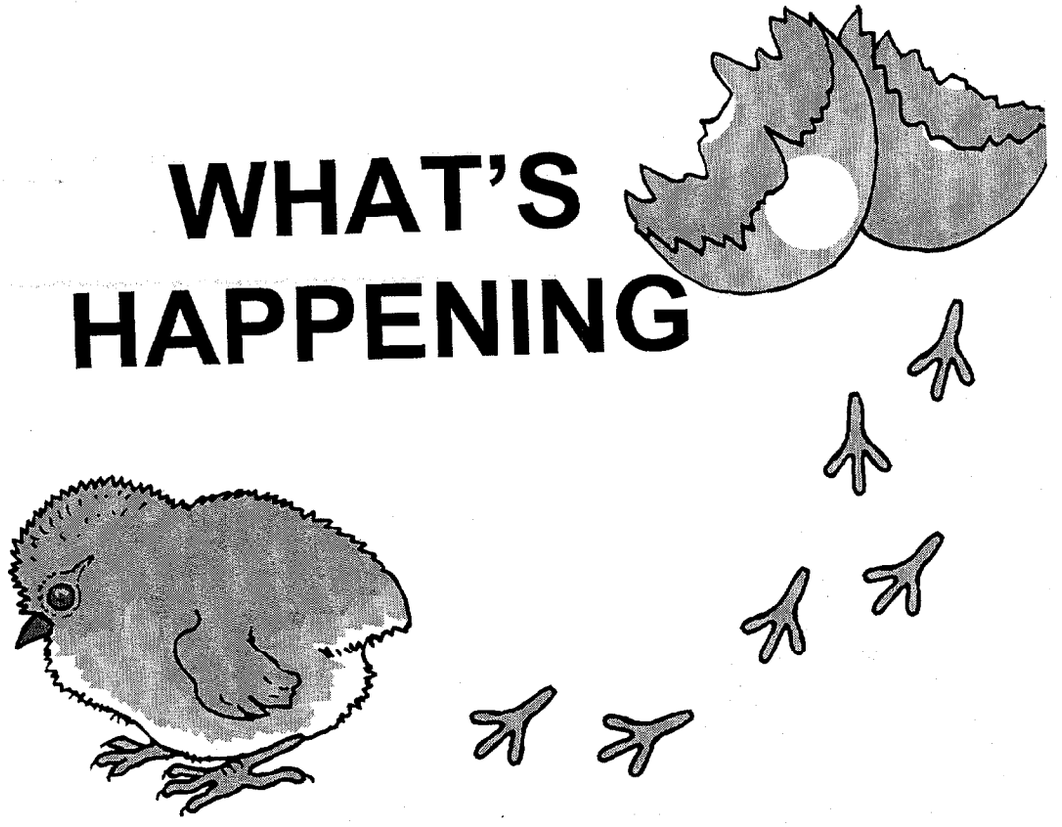
M703

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANAUFACTURERS (NAPM) MID-YEAR MEETING NEWARK, NEW JERSEY MAY 15, 2000

ROBERT L. WEST, M.S. R. Ph.
ACTING DEPUTY DIRECTOR
OFFICE OF GENERIC DRUGS
CENTER FOR DRUG EVALUATION AND RESEARCH

DIVISION OF LABELING AND PROGRAM SUPPORT

WHAT'S HAPPENING



LABELING ISSUES

1. GUIDANCE FOR INDUSTRY - PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT-NDAs
   (Final January 1999)
   http://www.fda.gov/cder/guidance/index.htm

   - Page 13 - Labeling

2. ANDA GUIDANCE IN DEVELOPMENT
   - Statement that proposed labeling is the same as that of the RLD
     - Differences annotated and explained
     - Labeling for RLD

PARAGRAPH IV CERTIFICATIONS

ON THE INTERNET

http://www.fda.gov/cder/ogd

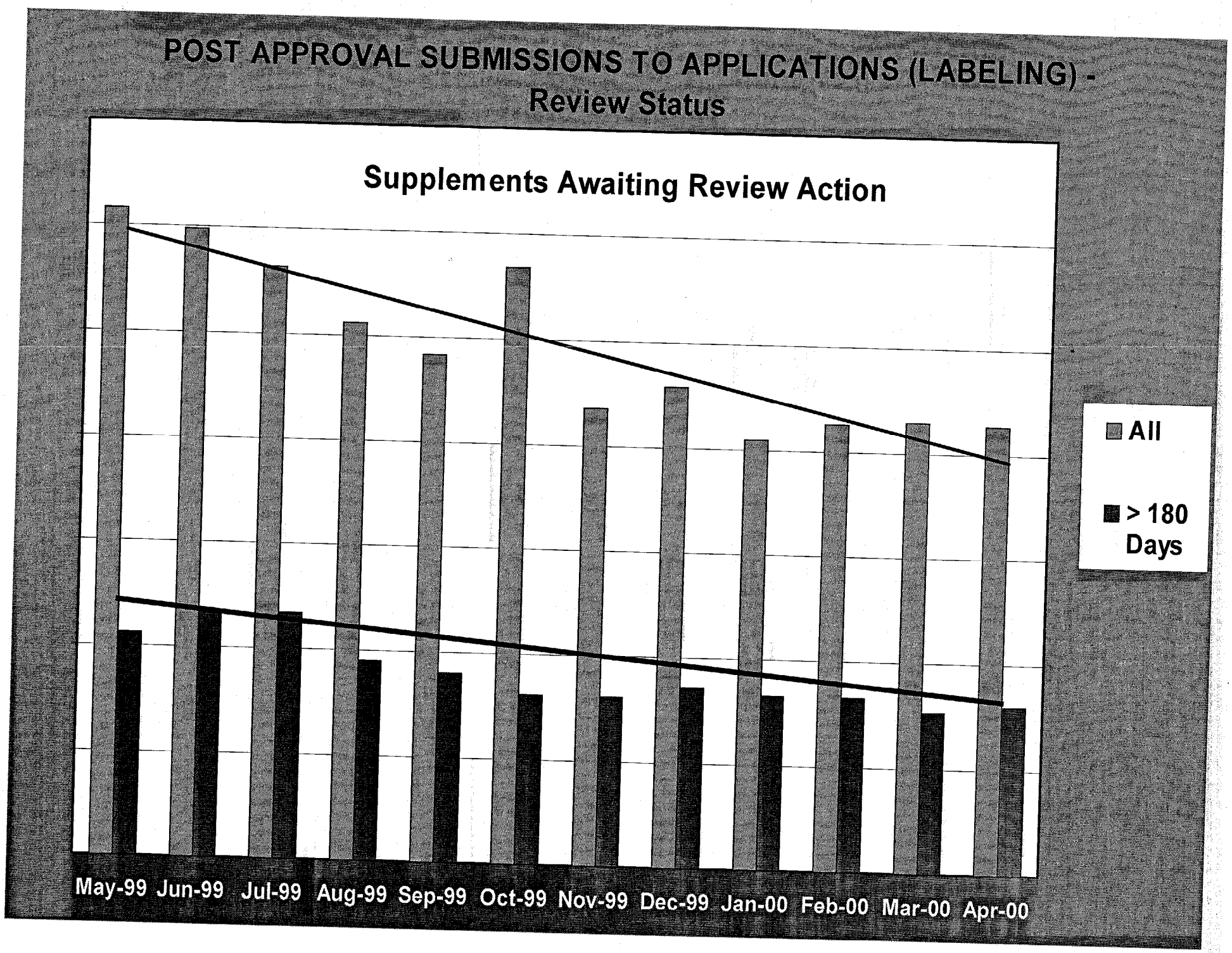
- PILOT PROJECT TO BE STARTED
- Upon filing will list the first generic ANDA with a Paragraph IV Certification
    - Generic Name
    - Dosage Form
    - Strength(s)
    - RLD and NDA Holder
    - Located on the OGD Homepage

■ Cautions

- Absence of a drug product on the list does not assure that a Paragraph IV Certification has not been received

- Information will continue to be provided in response to telephone inquiry
  (301) 827-5862 - REGULATORY/SUPPORT BRANCH

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING) - Review Status



MORE TOPICS

1. Guidance for Industry-Revising ANDA Labeling Following Revision of the RLD Labeling
   - •Shifts responsibility from OGD to firm
   - http://www.fda.gov/cder/ogd/rld/labeling review branch.htm
   - Exceptions

     Labeling changes that warrant immediate notification

2. ANDA withdrawal project