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: February 14, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Dispute Resolution

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: Dispute Resolution

Presented for: NAPM

Date Presented: October 12, 2000

Presented by: Gary Buehler, Acting Director
Office of Generic Drugs

Number of Pages: 10

Melissa Lamb

Attachment

90S-0308

M693

Dispute Resolution

National Association of
Pharmaceutical Manufacturers
2000 Fall Technical Workshop
October 12, 2000

Gary Buehler, Acting Director
Office of Generic Drugs

- Regulatory Support
- Bioequivalence
- Chemistry/Microbiology
- Labeling
- Field/Review Issues

Regulatory Support

- Refuse to Receive (RTR)
  - Fewer RTRs
  - 10 days to respond to t-con issues
- Inactive Ingredients
  - Include any data for questionable inactive ingredients
  - If data provided, RTR will be rescinded
- Bioequivalence Study
  - Every first generic sent to Division of Bioequivalence (DBE) for initial read

Regulatory Support

- Procedure
  - Contact Regulatory Support Directly
    Phone: 30 l-827-5862
- Appeal
  - Division Director - Peter Rickman
    Acting Director, DLPS
    30 l-827-5846
  - Office Director - Gary Buehler
    Acting Director, OGD
    30 l-827-5845

Bioequivalence

- New Methodologies
  - DPK, Exhaled nitric oxide
- Study Fails Due to Outlier
  - Can restudy with 3-4 subjects from original study
- Waivers
  - Use highest strength unless issues on:
    - Safety
    - Fairness

Bioequivalence

- Specifications/Dissolution
- Division of Scientific Investigations (DSI) Inspections
  - Retained Samples
  - Document which subject received which drug

Bioequivalence

- Procedure
  - Contact Project Manager (PM)
    Phone: 301-827-5847
  - Send disputes in writing
  - Often resolved in t-con with Division Director (DD)
- Appeal
  - Office Director - Gary Buehler

Chemistry

- Amendment Designation -

  Major/Minor/FAX/Telephone

  - Decision made at reviewer/Team Leader (TL) level
  - Appeal to DD/Deputy DD
  - Send disputes in writing (FAX to PM)
  - Final appeal to Office Director

Chemistry

- Supplement Designation
  - Prior AP / CBE / CBE-30 / AR
  - Cover letter should be specific
  - Decision made at team level
  - Note clearly if part of a global set
  - First discuss with TL/reviewer

Chemistry

- Specifications/Deficiencies Identified Late in Review Process
  - Working Internally to Address Earlier in the Process (TL Level)
  - Data Sometimes Not Available
  - Done to Improve Consistency

Chemistry

- Supplement Designation Guidance
- PAC 3 14.70 Email: pac3 14_70@cder.fda.gov
- Questions Sent Directly to Nancy Sager, OPS
- Responses Discussed at 5 DDs meeting

Chemistry

- Procedure
  - Contact Project Manager/Team Leader to discuss
  - Send disputes in writing to avoid misunderstanding
    - ☞ FAX to PM/TL
- Appeal
  - Division Director, Deputy Division Director
  - Then to Office Director
    - ☞ Controlled Correspondence

Microbiology

- Status Questions to Project Manager
- Micro Review is Not Started Until Chemistry Review Close to Approval
- Disputes Should be in Writing and Faxed to Project Manager
- Disputes Discussed with Team Leader and Reviewer
- Response Usually Within One Week

Labeling

- Minor Issues Handled in Labeling Branch through Correspondence to Applications
- Major Issues Usually Involve Patents/Exclusivity
- Often Involve Legal Issues
- Controlled Correspondence

Field/Review Issues

- Contact the Project Manager
- Often Identified by OGD Through Review of 483 or EIR
- Have Decreased Significantly Since Providing More Information to the Field
- Reviewer Will Discuss with Field
- Outcome Documented in Application
- Deficiencies from Investigator Can be Discussed with OGD

Resolution

- Informal
- Formal

Informal

- Within Division
- Division Director
- Office Director
  - Controlled Correspondence

Informal - Outside OGD

- PAC 3 14.70 E-mail Account
- 5DDs
- Ombudsman - Jim Morrison

Formal - Guidance

- Label as Formal Dispute Resolution
- Sent to Director, OGD
- Can Appeal further to:
  - ☞ Director, Office of Pharmaceutical Science
  - ☞ Director, CDER
- Should Not be Based on New Information
- Can Request Advisory Committee Review