

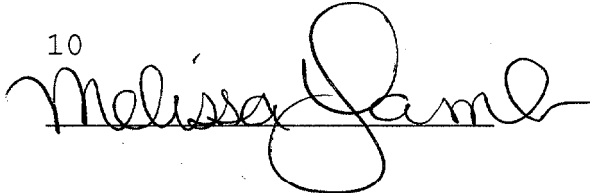
M E M O R A N D U M

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



Attachment

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90S-0308

M 693

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 - ◆ If data provided, RTR will be rescinded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 1-827-5862
 - Appeal
 - ◆ Division Director - Peter Rickman
Acting Director, DLPS
30 1-827-5846
 - ◆ Office Director - Gary Buehler
Acting Director, OGD
30 1-827-5845
- 

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@cderr.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
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Informal

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