

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: November 26, 2002
To: Dockets Management Branch (HFA-305)
From: Lafayette Gross
Office of Generic Drugs
Subject: The FDA Process for Approving Generic Drugs

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: The FDA Process for Approving Generic Drugs
Presented for: Blue Cross Blue Shield of Michigan
Continuing Medic/Pharmacy Association
Date Presented: October 29, 2002
Presented by: Gary Buehler, R.Ph, Director
Number of Pages: 9



Attachment

90S-0308

M 729

Blue Cross Blue Shield
of Michigan
Continuing
Medical/Pharmacy
Education Program



The FDA Process for Approving Generic Drugs

Gary J. Buehler, R.Ph
Director

October 29, 2002

Did you know that generic drugs...

- Are safe and effective alternatives to brand name prescriptions
- Can help both consumers and the government reduce the cost of prescription drugs
- Are currently used in 44% of all prescriptions dispensed

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And...

- Save an average of \$45.50 for every prescription sold
- Currently save consumers \$56.7 billion/year
- Can save consumers an additional \$1.32 billion/year for every 1% increase in the use of generic drugs

Source: National Association of Pharmaceutical Manufacturers, December 15, 2000

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Hatch-Waxman Amendments to FFD&C Act - 1984

- Considered one of the most successful pieces of legislation ever passed
- Created the generic drug industry
- Increased availability of generics
 - 1984 12% prescriptions were generic
 - 2000 44% prescriptions were generic - yet only 8% of revenue for prescription drugs
- Compromise legislation to benefit both brand and generic firms

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4

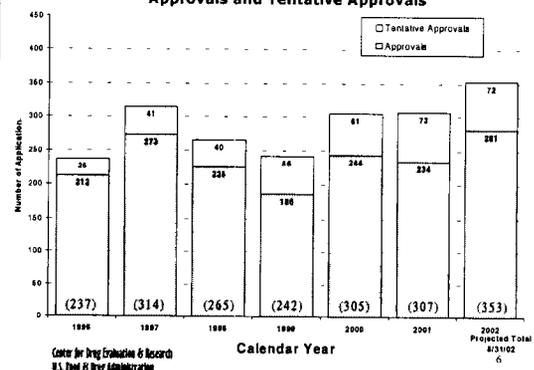
Hatch-Waxman Amendments to FFD&C Act - 1984

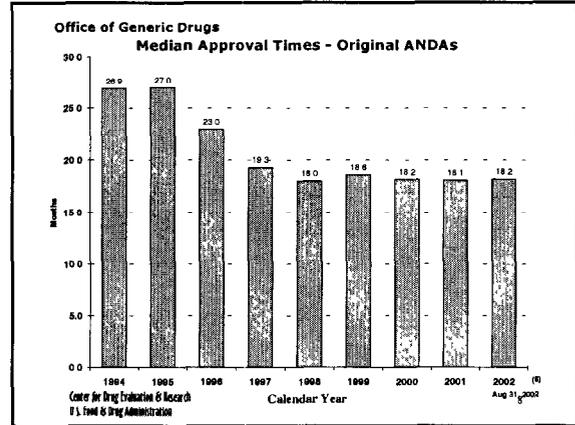
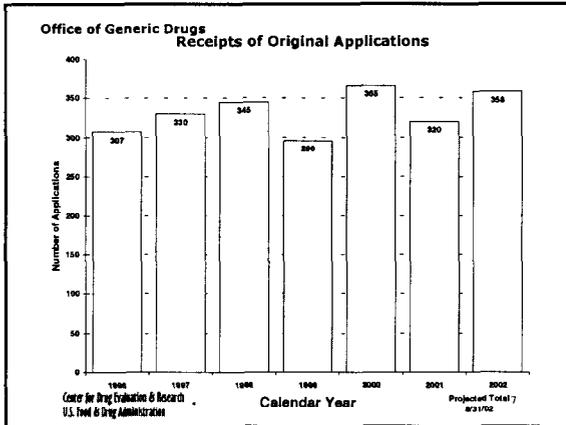
- Allowed generic firms to rely on findings of safety and efficacy of innovator drug after expiration of patents and exclusivities (do not have to repeat expensive clinical and pre-clinical trials)
- Allowed patent extensions and exclusivities to innovator firms

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Office of Generic Drugs Approvals and Tentative Approvals





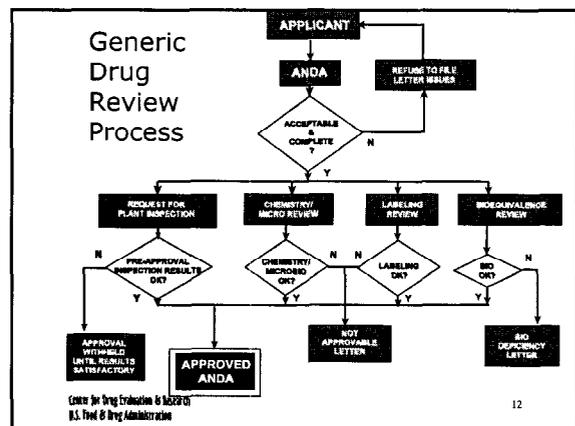
NDA vs. ANDA Review Process

Brand Name Drug NDA Requirements	Generic Drug ANDA Requirements
1. Chemistry	1. Chemistry
2. Manufacturing	2. Manufacturing
3. Controls	3. Controls
4. Labeling	4. Labeling
5. Testing	5. Testing
6. Animal Studies	6. Bioequivalence
7. Clinical Studies	
8. Bioavailability	

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- ### What are the requirements for a generic drug?
- Labeling
 - Chemistry/Microbiology
 - Bioequivalence
 - Legal
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- ### How do we assure the quality of generic drugs?
- First 5 steps of review process are identical to NDA process
 - Bioequivalence for complicated products is discussed with the same staff that reviewed the brand product
 - FDA has experience with the product
 - Scientific literature published
 - Product is known to be safe
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What are the requirements for a generic drug?

- Same active ingredient(s)
 - Same route of administration
 - Same dosage form
 - Same strength
 - Same conditions of use
- Compared to reference listed drug (RLD)
- (brand name product)

Labeling

- "Same" as brand name labeling
- May delete portions of labeling protected by patent or exclusivity
- May differ in excipients, PK data and how supplied

Chemistry

- Components and composition
- Manufacturing and controls
- Batch formulation and records
- Description of facilities
- Specs and tests
- Packaging
- Stability

Examples of Information Covered in a Chemistry Review

- Qualitative and quantitative listing of all active and inactive ingredients; including grade of each component

Examples of Information Covered in a Chemistry Review

- Review of manufacturing and controls includes evaluation of:
 - Process for manufacturing
 - Controls (Inspections, sample points, test, methods, acceptance criteria) in place from the receipt of the raw material to the labeling and storage of the finished product; includes the Certificate of Authorization (COA) from the raw material manufacturer and the firm's own testing and specifications in a COA
 - Synthesis of the active pharmaceutical ingredient(s) (API) (raw material, drug substance) or authorization to reference a Drug Master File (DMF)

Examples of Information Covered in a Chemistry Review

- Impurity profile of the API
- Stability of the API
- Characterization of degradation products with drug substance and drug product
- Microbiological testing when appropriate (Reviewed by Microbiologists)

Examples of Information Covered in a Chemistry Review

- Batch formulation and batch records
 - Manufacturing record provides a representation of the formula, manufacturing instructions, description and size of manufacturing equipment



Examples of Information Covered in a Chemistry Review

- Description of the manufacturing facilities in general; identification of all firms and facilities involved
- Stability profile (with information on such things as container/closure system); adequacy of protocol and methods
- Evaluation of methods validation information prior to laboratory evaluation

Examples of Information Covered in a Chemistry Review

- Container/Closure Systems
- Environmental Assessment compliance

Manufacturing Compliance Programs

- Purpose - To assure quality of marketed drug products
- Mechanisms - Product Testing
 - Surveillance
 - Manufacturing/Testing plant inspections
 - Assess firm's compliance with good manufacturing processes

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

22nd EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

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OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT & SERVICES

2002

Electronic Orange Book -
<http://www.fda.gov/cder/ob/>

“Orange Book”



- All FDA approved drug products listed (NDA's, OTC's & ANDA's)
 - Therapeutic equivalence codes
 - "A" = Substitutable
 - "B" = Inequivalent, NOT Substitutable
 - Expiration dates: patent and exclusivity
 - Reference Listed Drugs/brand drugs identified by FDA for generic companies to compare with their proposed products

B-Rated Drugs

- Exist because of the evolution of FFD & C Act
 - FFD & C Act 1938 - safety only
 - 1962 Amendments - Added effectiveness requirement
 - DESI program to assess efficacy of drugs approved between 1938 and 1962
 - 1970 - Regulation initiating the ANDA procedure

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Continued
25

B-Rated Drugs

- 1977 - Bioavailability/Bioequivalence (BA/BE) regulations finalized
 - Required BA data in NDAs; BE data in ANDAs
 - Divided DESI effective drugs - products that needed BE shown in vivo and in vitro (bio problem drugs) and products that BE may be shown in vitro only (non-bio problem drugs)
- Many bio problem drugs approved as safe and effective before 1977 - in vivo determination of BE deferred for reasons such as inadequate methodology
- FDA determined BA/BE regulations could not be used retrospectively

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26

B-Rated Drugs

- 1984 Hatch-Waxman - gave FDA statutory authority to require a demonstration of BE before an ANDA could be approved. No longer allowed approval of bio problem drugs
- Products for which in vivo demonstration of BE was deferred are listed as therapeutic inequivalent or "B" rated
- Those still appearing in the Orange Book are about 3% - FDA does not have data demonstrating equivalence or inequivalence

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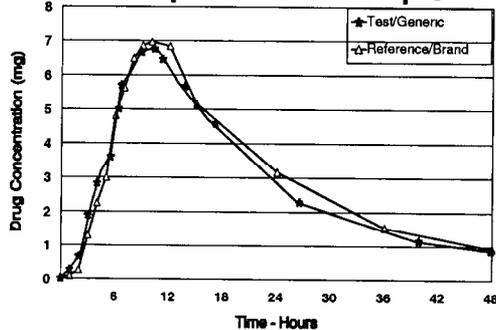
Definition of Bioequivalence

Pharmaceutical equivalents whose rate and extent of absorption are not statistically different when administered to patients or subjects at the same molar dose under similar experimental conditions

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Bioequivalence Example



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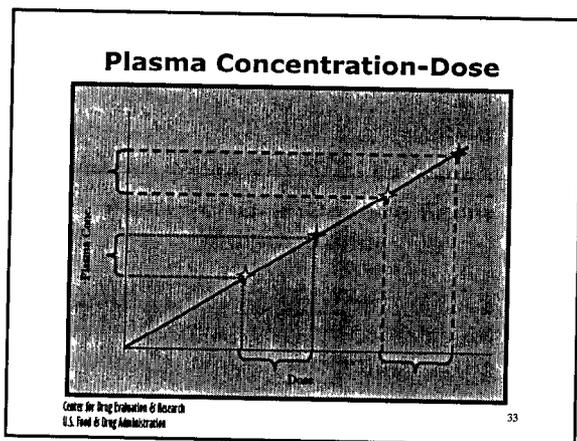
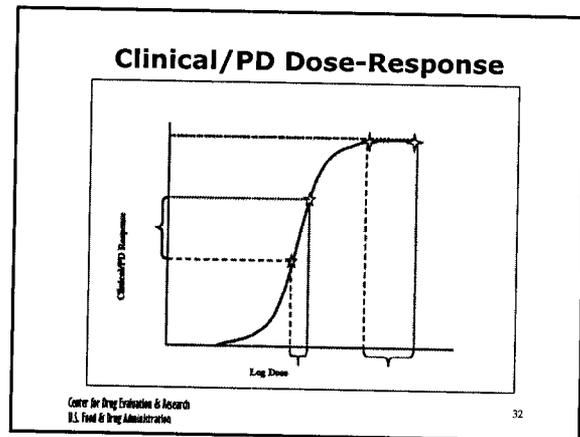
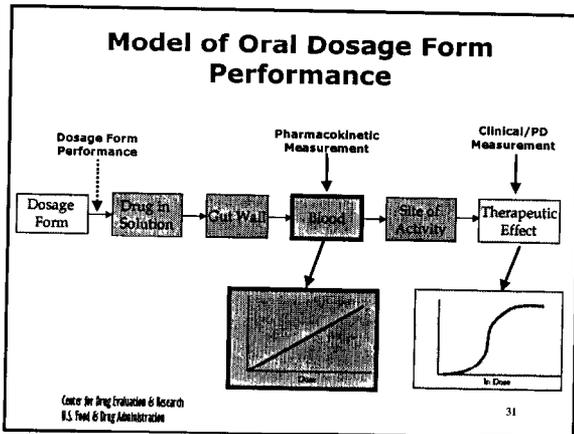
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Purpose of BE

- Therapeutic equivalence (TE)
- Bioequivalent products can be substituted for each other without any adjustment in dose or other additional therapeutic monitoring
- The most efficient method of assuring TE is to assure that the formulations perform in an equivalent manner

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- ### Approaches to Determining Bioequivalence (21 CFR 320.24)
- In vivo measurement of active moiety or moieties in biologic fluid
 - In vivo pharmacodynamic comparison → FeV₁, Albuterol, Blanching Study, Topical Corticosteroid
 - In vivo limited clinical comparison → Topicals, Nasal Suspensions
 - In vitro comparison → Questran - Binding Studies, Nasal Solutions-Sprayer Evaluation, Propofol - Droplet Size
 - Any other approach deemed appropriate by FDA
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- ### Study Designs
- Single-dose, two-way crossover, fasted
 - Single-dose, two-way crossover, fed
 - Alternatives
 - Single-dose, parallel, fasted → Long Half-Life (wash-out) Amodarone, Etidronate
 - Single-dose, replicate design → Highly Variable Drugs
 - Multiple-dose, two-way crossover, fasted → Less Sensitive Clozapine (Patient Trials) Chemotherapy Trials
 - Clinical endpoint study → Topicals Nasal Suspensions
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- ### Waivers of In Vivo Study Requirements
- Definition
 - Criteria (21 CFR 320.22)
 - In vivo bioequivalence is self-evident
 - Parenteral solutions
 - Inhalational anesthetics
 - Topical (skin) solution
 - Oral solution
 - Different proportional strength of product with demonstrated BE
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Statistical Analysis (Two One-sided Tests Procedure)

- AUC and Cmax
 - 90% Confidence Intervals (CI) must fit between 80%-125%

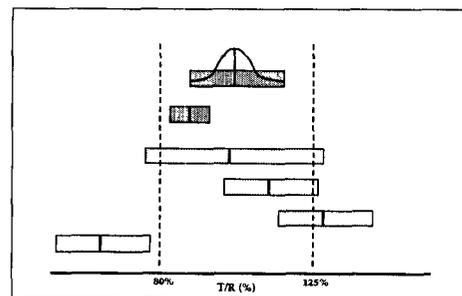
Statistical Analysis 80 - 125 %

- What does this mean?
- Can there be a 46% difference?
- What is a point estimate?
- What is a confidence interval?

Statistical Analysis

- Bioequivalence criteria
 - Two one-sided tests procedure
 - Test (T) is not significantly less than reference
 - Reference (R) is not significantly less than test
 - Significant difference is 20% ($\alpha = 0.05$ significance level)
 - $T/R = 80/100 = 80\%$
 - $R/T = 80\%$ (all data expressed as T/R so this becomes $100/80 = 125\%$)

Possible BE Results (90% CI)

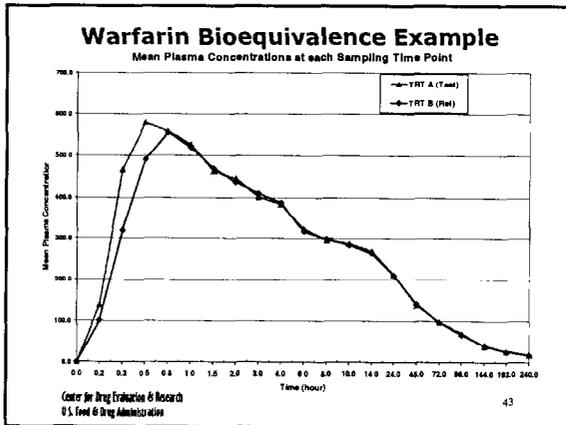


Narrow Therapeutic Range (NTI) Drugs

- Drug Products that are subject to therapeutic drug concentration or pharmacodynamic monitoring
 - Examples are: Digoxin, Lithium, Phenytoin, Warfarin
- Traditional bioequivalence limit of 80-125% is unchanged for these products

Generic Warfarin 10mg Tablets

	AUC _{0-t}		AUC _{0-∞}		Cmax	
	PI	CI	PI	CI	PI	CI
Applicant # 1	1.02	(98.8-105)	0.98	(95-100)	1.02	(95.1-110)
Applicant # 2	1.00	(97-102)	1.00	(97.4-102.4)	0.99	(90-100)
Applicant # 3	0.99	(96-102)	1.03	(100.4-105.7)	0.94	(89-99)



- ### In Vivo Bioequivalence Inspections
- Covers clinical and analytical components
 - Objectives
 - Verify quality and integrity of the scientific data
 - Ensure rights and welfare of human subjects are protected
 - Ensure compliance with the regulations and promptly follow-up on significant problems (research misconduct; fraud)
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- ### Generic Drug Education Program
- Congress acknowledged overall need for educational program
 - FY02 \$400,000 allocation
 - Program to educate the public on the quality of generic drug products
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- ### Physician Focus Group Findings
- MDs know little about FDA review and approval process--especially how it differs for generic products
 - Lack of knowledge and understanding of bioequivalence (sameness) evaluation testing
 - "Placebo" effect - product looks different
 - Need more information
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- ### Getting the Message Out
- Target health care providers (Physicians, Pharmacists) as well as consumers
 - Continuing Education (CE) Programs
 - Office of Training and Communications (OTCOM) Specialists in CDER
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- ### Educational Program Activities
- | | |
|------------------------|-------------------|
| Print PSA | Focus Testing |
| Brochures | NAPs Article |
| Posters | Give-Aways |
| Web Site Consumer Page | Bus/Train Ads |
| Magazine Ads | Movie Theater Ads |
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**Generic Drug Education Program
Posters**

Contact: Ellen Shapiro
Director, Div. of Public Affairs
Center for Drug Evaluation and Research
phone: 301-827-1667

Web address:
www.fda.gov/cder/consumerinfo/DPAdefault.htm

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52

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53

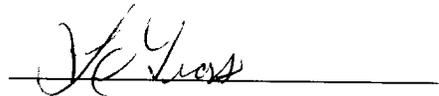
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: November 26, 2002
To: Dockets Management Branch (HFA-305)
From: Lafayette Gross
Office of Generic Drugs
Subject: Division of Bioequivalence Update

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: Division of Bioequivalence Update
Presented for: GpHA Fall Technical Workshop
Date Presented: October 15, 2002
Presented by: Dale P. Conner
Division of Bioequivalence, OGD
Number of Pages: 16



Attachment

90S-0308

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Division of Bioequivalence Update

GPhA Fall Technical Workshop

Dale P. Conner

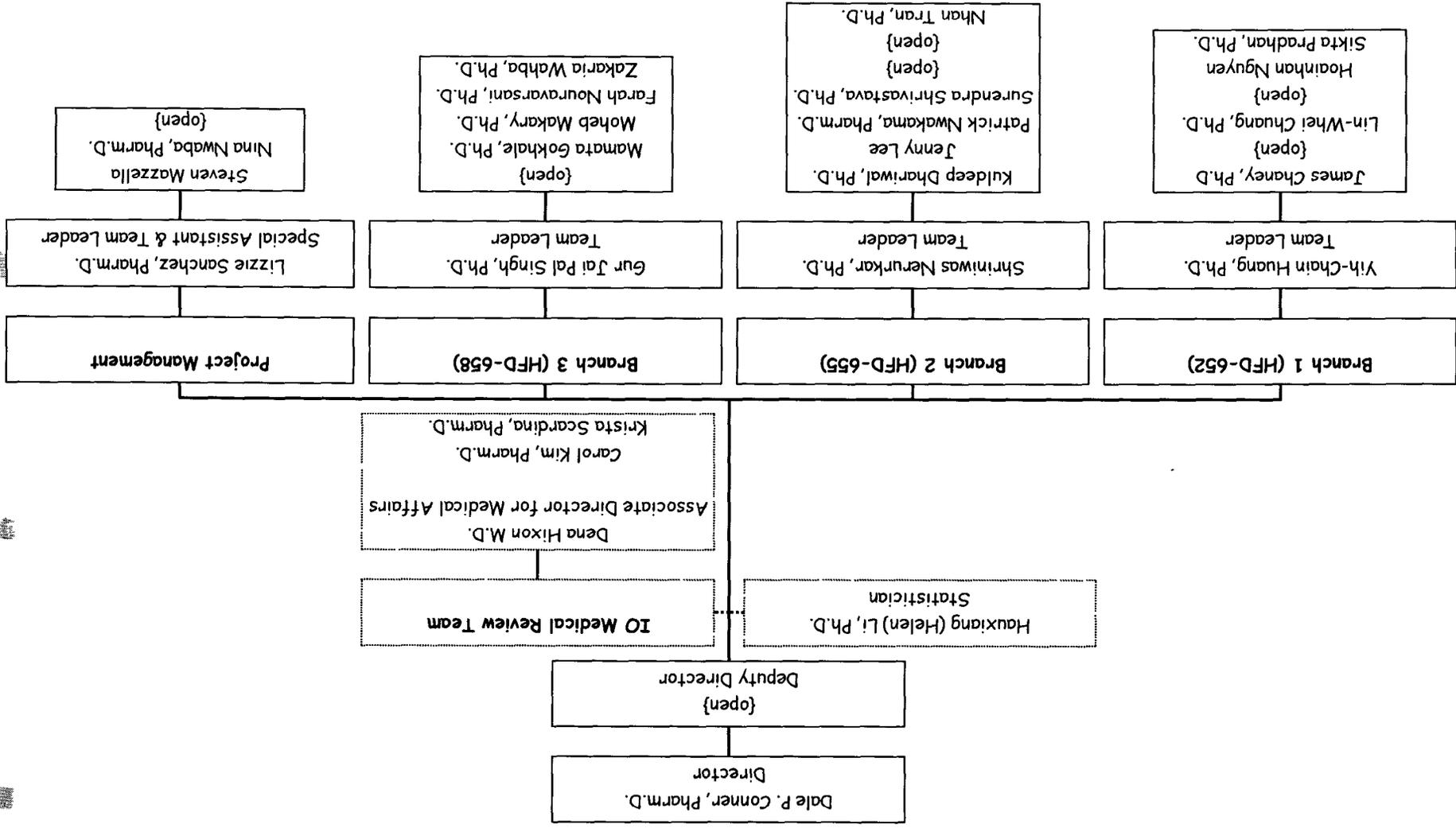
Division of Bioequivalence, (

For the
Docket

Introduction

- Structure of Division of Bioequivalence
- Various BE Issues/Questions

Division of Bioequivalence



Current DBE Backlog

- Control Documents
 - Duplicates
 - Multiple products in single document
 - Lower priority than ANDAs
- ANDA
 - Queue

New Review Format

- Center initiative to standardize review formats
- DBE is currently developing review template
 - Standardize review format
 - Streamline completion of review documents by reviewers
 - Make future information retrieval more efficient
- Data should be submitted in SAS Transport

Guidances

- Good Guidance Practices (GGPs) 21 CFR 10.115
- Comments can be submitted at any time to any guidance
- Guidances can be drafted and submitted for consideration by interested parties

Guidances

- BA/BE
- Fed BE
- Clozapine
- Topical Antifungal
- Nasal Products

Replicate Design vs. Two-Way

Crossover

- Current general BA/BE guidance recommends replicate design for MR products
- New draft guidance changes this recommendation
- Either design is acceptable
- Analysis is by average BE

Reserve Sample Retention

- 21 CFR 320.63 and 21 CFR 320.38
- Continues to be a problem
- Problems frequent in bioequivalence studies with clinical end-points
- Clinical investigator should choose test article samples for retention
- Draft guidance published for comment

Food-Effect BE Studies

- Currently
 - If a food effect (even a negative one) on bioavailability is mentioned in the labeling a fed BE study should be submitted
 - If the labeling instructions say to **ONLY** take on an empty stomach then a fed BE study is not necessary

Food-Effect BE Studies

- **Currently**
 - **Two-way crossover studies**
 - **Point estimates should fall within 80 - 125%**
 - **No waivers of fed-BE studies for BCS Class 1 drugs (yet)**
- **Draft Guidance**
 - **90% Confidence interval criteria**
 - **BCS waivers for fed BE studies for Class 1**

Date of Implementation of Guidances

- Date may be stated in the guidance
- If not stated it is usually on the date of issuance of the final copy
- If you have a pending deficiency and a new guidance seems to say that this is no longer a deficiency -- consult the appropriate review division

Biopharmaceutics Classification System (BCS)

- Few ANDA submissions
- Almost none contain permeability data performed by sponsors
- Literature data?
- FDA has tentative plans to classify some compounds

“Failed” Studies

- Agency is requesting submission of “failed” or additional studies
- Studies on the “final” formulation
- These studies to be submitted as complete summaries
- Clarification of regulations is planned
- Guidance is also planned after regulation changes are finalized

Pharmacokinetic Reassays

- Reassay of samples for “pharmacokinetic” reasons
- This is discouraged, but if you do it
- Objective a priori criteria should be stated in SOP
- Provide a complete before and after data analysis

In Vitro Dissolution

- Provide laboratory site information
- DSI inspections are planned

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Director, Office of Generic Drugs
Number of Pages: 9



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Generic Pharmaceutical Association
2002 Fall Technical Workshop



Office of Generic Drugs Update

Gary J. Buehler, R.Ph.
Director, Office of Generic Drugs
October 15, 2002

Topics

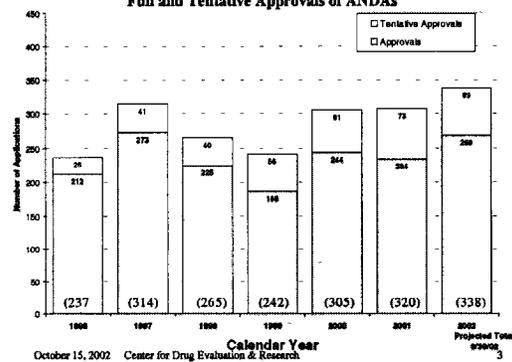
- Office Productivity - Review of Actions
- Budget Appropriations
- Initiatives
- Education Programs
- Electronic Submissions Update

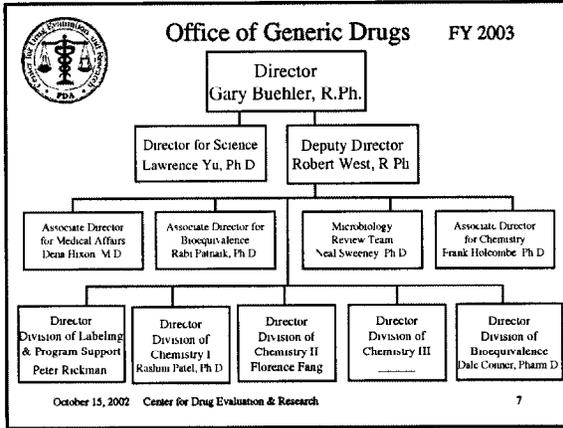
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Office of Generic Drugs

Full and Tentative Approvals of ANDAs





Microbiology Review

- Hired New Team Leader
- Plan to Hire 2 Additional Reviewers (to make a total of 6)
- Backlog is Decreasing, But Still Unable to Review Originals on 1st Cycle
- Looking to Improve Efficiency of Review Through Use of Telephone
- Micro Review Copy

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Orange Book

- Orange Book (OB) Staff Has Been Moved from Office of Information Technology (OIT) to OGD
- Move will Facilitate Communication Between OB Staff and Regulatory Support Team
- Plan to Improve Efficiency of OB Operation (Patent Listing and OB Revisions)

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FY 2002 Appropriations

- Targeted:
 - Increased Staffing
 - Dollars for Public Awareness Program

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10

FY2003 Budget Issues

- House Appropriations \$4.6M
- Senate Appropriations \$6.0M

- 2003 FTE increase - 30
- Research Initiatives

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Research Initiatives

- Respond to Scientific Challenges
- Develop Bioequivalence Methods
 - MDIs
 - Topicals
 - Injectable Suspensions
 - Liposomes ?
 - Complex Drugs

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12

OGD Research Initiatives Committee

- Lawrence Yu, Ph.D.
- Frank Holcombe, Ph.D.
- Rabi Patnaik, Ph.D.

Research Initiatives

- Expand In-House Capabilities
- Work with Office of Testing & Research in Developing/Hiring Expertise
- External Contracts

Generic Drug Education Program

- Congress acknowledged overall need for educational program
- FY'02 \$400,000 allocation
- Program to educate the public on the quality of generic drug products

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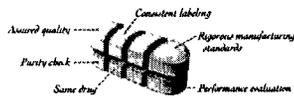
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Physician Focus Group Findings

- MDs know little about FDA review and approval process--especially how it differs for generic products
- Lack of knowledge and understanding of bioequivalence (sameness) evaluation testing
- "Placebo" effect - product looks different
- Need more information

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Getting the Message Out

- Target health care providers (Physicians, Pharmacists) as well as consumers
- Continuing Education (CE) Programs
- Office of Training and Communications (OTCOM) Specialists in CDER

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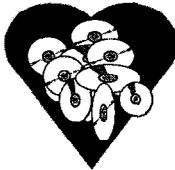
Educational Program Activities

Print PSA	Focus Testing
Brochures	NAPs Article
Posters	Give-Aways
Web Site Consumer Page	Bus/Train Ads
Magazine Ads	Movie Theater Ads

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Electronic Regulatory Submissions



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Providing Regulatory Submissions in Electronic Format--ANDAs

- Provides for consistency with current NDA format
- Provides for consistency and ease of transition to e-CTD format
- Enhances the review process - search/retrieving information, copy/paste into review
- Highly Encouraged!

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Why Electronic Submissions?

- Many believe it is the best way to meet established and new review goals
- Convenient / Faster
- Efficient (time saving)
- Space Saving
- CDER enjoys these advantages - why shouldn't you???



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24

More Information

www.fda.gov/cder/regulatory/ersr/default.htm

www.fda.gov/cder/m2/eCTD.htm

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25

Final Words...

- New Era for OGD - (\$)
- Increase our Efficiency and Responsiveness
- Develop Validated Bioequivalence Methods for Certain Drug Products
- Enhance and Expand our Science Base so that All Decisions are Well Grounded
- Confront and Address the Multiple Legal Issues

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26

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27
