USA Proprietary Name Review Process

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Surveillance and Epidemiology (OSE)
Division of Medication Errors and Prevention (DMEDP)

Proprietary Name Review - Safety

- Focus of review – avoid and prevent medication errors
- Evaluate name and error-prone aspects of:
  - Labels
  - Labeling
  - Packaging
  - Product Design

CDER Review of Proprietary Names

- Review performed by Office of New Drugs (various clinical divisions) and Office Generic Drugs (OND & OGD) in consultation with other CDER offices/divisions
  - Office of Surveillance and Epidemiology/DMEDP
  - Office of Medical Policy/DDMAC
  - Joint review with CBER in some cases
  - Final Decision rests with OND & OGD

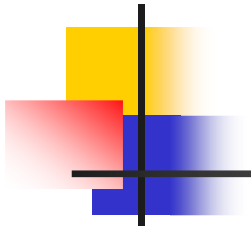
Pre-Marketing Review Process

- Name Analysis : Multi-factorial process
- Labeling and Packaging Analysis
- Overall Risk Evaluation
- Written Recommendation Provided to Division

CDER Proprietary Name Review

- Name Analysis Begins:
  - End of Phase II or New Drug Application (NDA) or Biologics License Application (BLA) or Abbreviated New Drug Application (generics) (ANDA)
  - Sponsors submit 2 names
    - Primary (1st choice)
    - Secondary (2nd choice)
- Name Reviewed:
  - Investigational New Drug (IND) and/or NDA/BLA/ANDA & 90 days prior to approval
- Product Characteristics must be known for analysis to BEGIN

Product Characteristics



- Any or all characteristics of product can increase or decrease risk, and MUST be considered in risk assessment of name:
  - Drug Name (Generic & Brand name, Suffix ,etc)
  - Dose, strength(s), dose form
  - Packaging
  - Physical attributes
  - Route
  - Frequency of administration
  - Instructions for use
  - Storage requirements
  - Indications, patient population
  - Likely care environment
  - Contraindications, etc.

Contributing Factors

- Overlapping strengths or dosing intervals
- Same patient and prescriber populations
- Identical formulations
- Similar indications for use
- Similar storage location
- Other

Pre-Marketing Multi Faceted Review

- **Expert Panel Review**
  - Medication Error Safety Evaluators + Division Drug Marketing Advertising and Communication (DDMAC)
  - Meet weekly
  - Rely on clinical, regulatory and professional experiences
- **Handwritten and Verbal Analysis**
  - Simulated drug name studies are sent to ≅ 120 FDA volunteers
  - The results provide a valuable tool for predicting potential confusion with marketed drugs

Pre-Marketing Multi Faceted Review

- Literature, textbook, and computer database searches
  - T&T Sagis, POCA, Drug Reference texts
- USAN (INN) Stem List
- Clinical experience of Safety Evaluators
- Lessons Learned from Post-marketing Experience
- Labeling and Packaging Analysis
  - Applying principals of Human Factors
- FMEA
  - Identifies failure causes
    - Where and how might confusion occur in the medication use system
    - Everyone in the medication use process considered
  - Determines failure effects
    - Can the confusion conceivably result in error in the usual practice


New / Changed Product Or Process
Marketing
Computers
Combo product
Abbreviations
Suffixes
Stress
Brand names
Doses
Legibility
Team
Nomenclature
Patient
Labels
Dose Regimens
Care Process
Communications
Care Setting
Culture
Dose forms
Routes
Fatigue
Knowledge
Work condition
Symbols
Indication
Language
Task
Generic names
Human factors
UBC
Storage
Packaging
Purchasing
Preparation
ERRORS !

Must Consider Medication Use System

- Prescriber population
- Prescribing & Ordering
- Clinical setting
- Purchasing
- Storage
- Delivery
- Administration
- Monitoring
- Therapy adjustments
- Duration of therapy
- Reordering
- Disposal
- External influences on the process

Considerations are Dependent on Type of Submission

- New Molecular Entity
- Product Line Extension
- Different proprietary names for the same active ingredient
  - Potential for confusion, overdosing, concomitant administration, allergies, hypersensitivity reactions
  - Generally discouraged
- Same proprietary name for different active ingredient
  - "Family" trade names for OTC products (e.g.,Dulcolax, Robitussin, Maalox)
  - Foreign trade name (e.g., Dilacor – Diltiazem U.S. and Digoxin in Serbia)
- Each type offers unique opportunities for error

DMEDP Philosophy

- CDER's Threshold for Name and Risk Assessment is set low because it is a **predictable** and **preventable** source that can often be *identified* and *remedied* prior to approval to avoid patient harm.

DMEDP Philosophy

- Post-approval efforts at reducing errors should be reserved for those cases in which *errors could not be predicted* prior to approval.
- **Prevention of error is the goal**.
- Reaction after a predictable error has already occurred is not sufficient.

Summary

- Drug names, labels, and packaging are major contributors to medication error
- Risk assessment includes product characteristics (not just names)
- Risk for error is determined by both drug product characteristics and the care system processes where drugs are used
- The predictable nature of errors provides opportunity for better name and product design to enhance safety