Medication Errors: An FDA Perspective

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Background

- Historically, nomenclature and design issues with packaging and labeling of drug products were identified and remedied post-marketing.
- Generally, the issues were resolved after medication errors had reached and harmed patients.
- Proactive and preventative approach today.
Exposing the Problem

• December 1999 IOM report
  – 48,000 to 98,000 people die yearly due to medical errors.
  – 7,000 of which are related to Medication Errors
  – Recommended FDA develop processes to evaluate proprietary names and labels/labeling to minimize medication error

• July 2006 IOM report
  – Major Problems with Naming Labeling and Packaging
  – Cause of 33% of medication errors, including 30% of fatalities
2006 IOM Recommendations

- Urged FDA to incorporate the principles of Human Factors analysis to address issues concerning information presentation in labeling and nomenclature.

- FDA require FMEA as part of the design and assessment of labeling and packaging for all prescription drug products.
Efforts on Naming, Labeling and Packaging

- **Contents of Complete Submission**
  - Finalized February 2010
  - http://Details product information needed for proprietary name name review
  - Review clock starts with a Complete Submission

- **Good Naming, Labeling, and Packaging of Drugs/Biologics to Reduce Medication Errors**
  - Based on Post-marketing Experience
  - Public Meeting held June 2010
  - Draft End of FY 10
  - Guidance too large – Split into 3 guidance's
    - Safety Considerations for Product Design to Minimize Medication Errors
    - Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors
    - Best Practices in Developing Proprietary Names

- **Best Test Practices for Proprietary Name Evaluation**
  - Concept Paper Basis for guidance
  - 2 years following accumulated data in Pilot Program
  - Public meeting to discuss results of pilot cancelled due to lack of participation
  - Combined into guidance #3 above
Guidance Program on Naming, Labeling and Packaging

- **Guidance 1: Safety Considerations for Product Design to Minimize Medication Errors**
  - Issued December 13, 2012
  - Comment period closed February 2013
  - Provides sponsors with a set of principles for developing RX and OTC drug products using a systems approach to minimize medication errors relating to product design
  - Describes methods for proactive risk assessments of proposed product design and the container closure
  - Recommendations based on postmarketing lessons learned

- **Guidance 2: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors**
  - Focuses on safety aspects of Rx container label and carton labeling design
  - Provides sponsors with a set of principles and recommendations for ensuring that critical elements of product labels and labeling are designed to promote safe use.
  - Recommendations based on postmarketing lessons learned

- **Guidance 3: Best Practices in Developing Proprietary Names to Minimize Medication Errors**
  - Joint Guidance with CBER
  - Combination of Concept Paper Plus Postmarketing Lessons Learned
    - Final paper issued October 2008
    - plus other recommendations for minimizing error based on postmarketing lessons learned
Human Factors of Medication Use

HF CONSIDERATIONS

- End User
- USE ENVIRONMENT
- Drug / INTERFACE

OUTCOME

SAFE & EFFECTIVE

UNSAFE, INEFFECTIVE
HF for Drug Products

• **End user**
  – Professional or non-professional
    • Patient, Caregiver, technician, or Healthcare Provider
    • May be all of above
  – Knowledge and Experience
  – Age and functional capabilities
  – Mental and Emotional Condition

• **Environment(s) of use**
  – Inpatient, outpatient, long term care, ambulance, home, etc.

• **Interface for Drug Product**
  – Container Closure and Actual Product Appearance
  – Product Design
  – Container label and Carton Labeling
The Medication Use System: Latent failure modeling

Questions