Label and Labelling Development: Strategies for Reducing Medication Errors

FDA/IMSN Joint Summit on Labelling and Packaging

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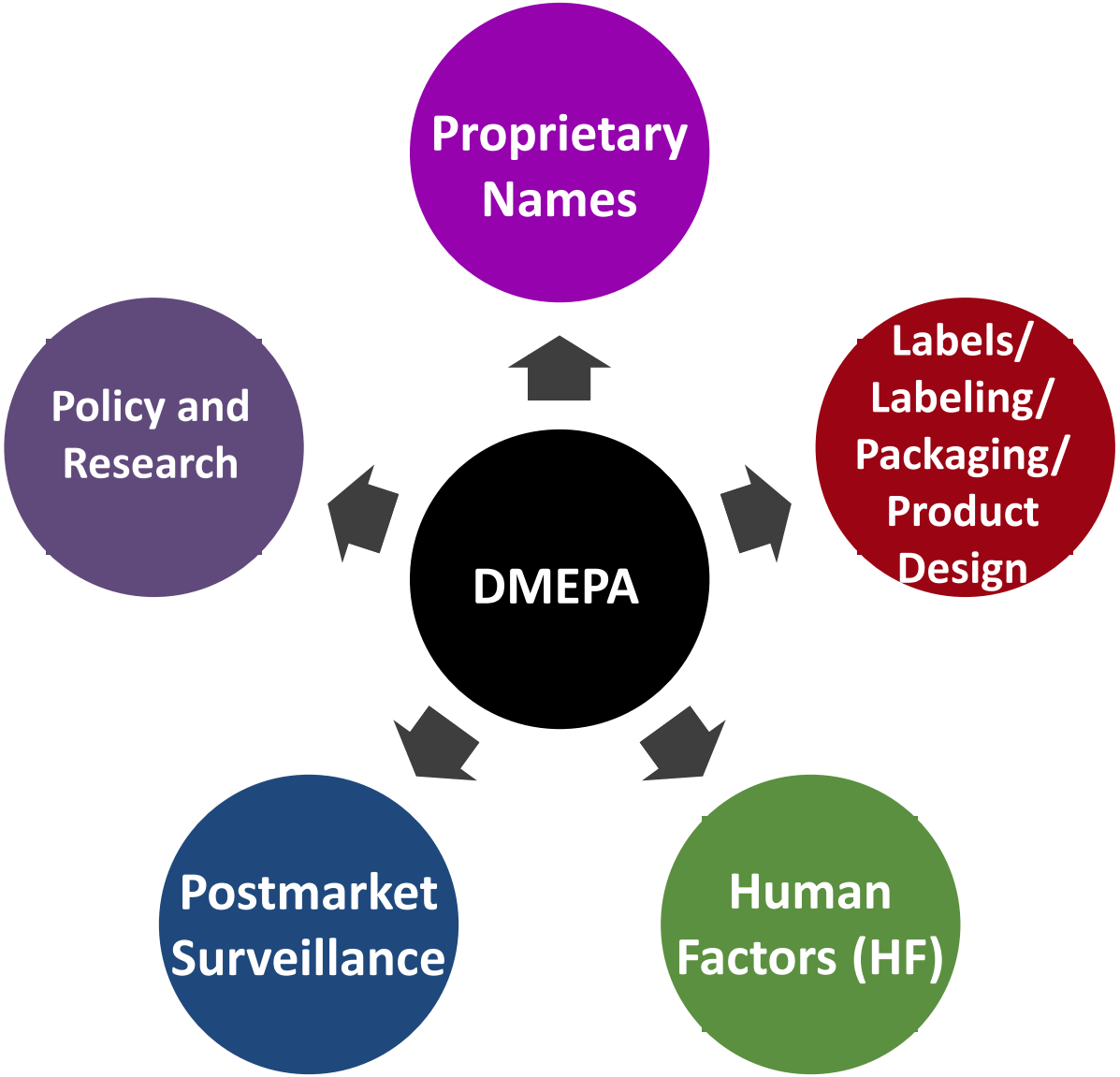
Division of Medication Error Prevention and Analysis (DMEPA)

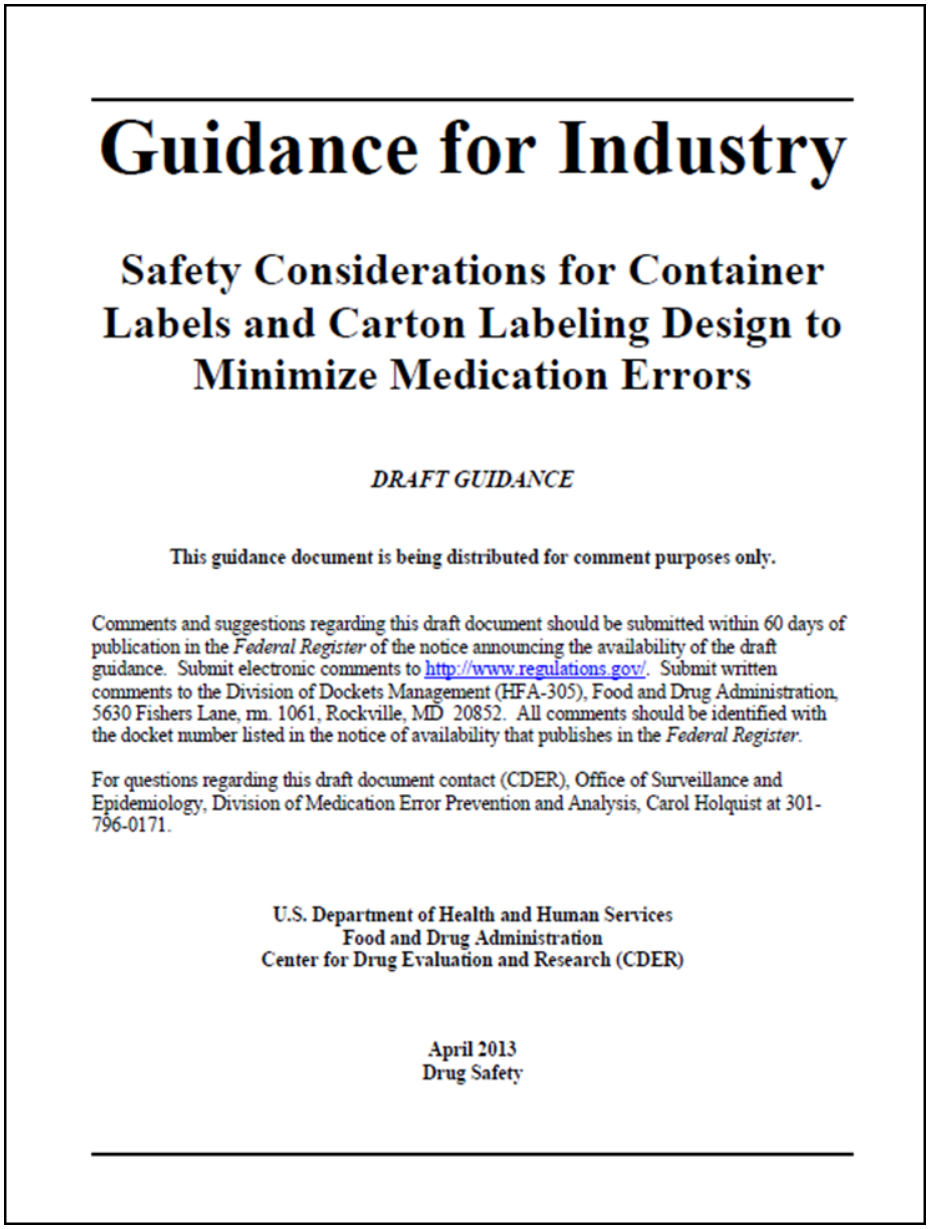
- Created in 1999
- Scientists and healthcare professionals with varied backgrounds
- 56 FTEs
- Aligned by therapeutic areas
- Leads CDER review pertaining to medication error prevention and analysis and human factors for drugs and therapeutic biologics

DMEPA Mission

To increase the **safe use** of drug products by minimizing use error that is related to the ***naming, labeling, packaging, or design*** of drug products

DMEPA Roles and Responsibilities





Guidance for Industry

Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov/. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER), Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Carol Holquist at 301-796-0171.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2013
Drug Safety

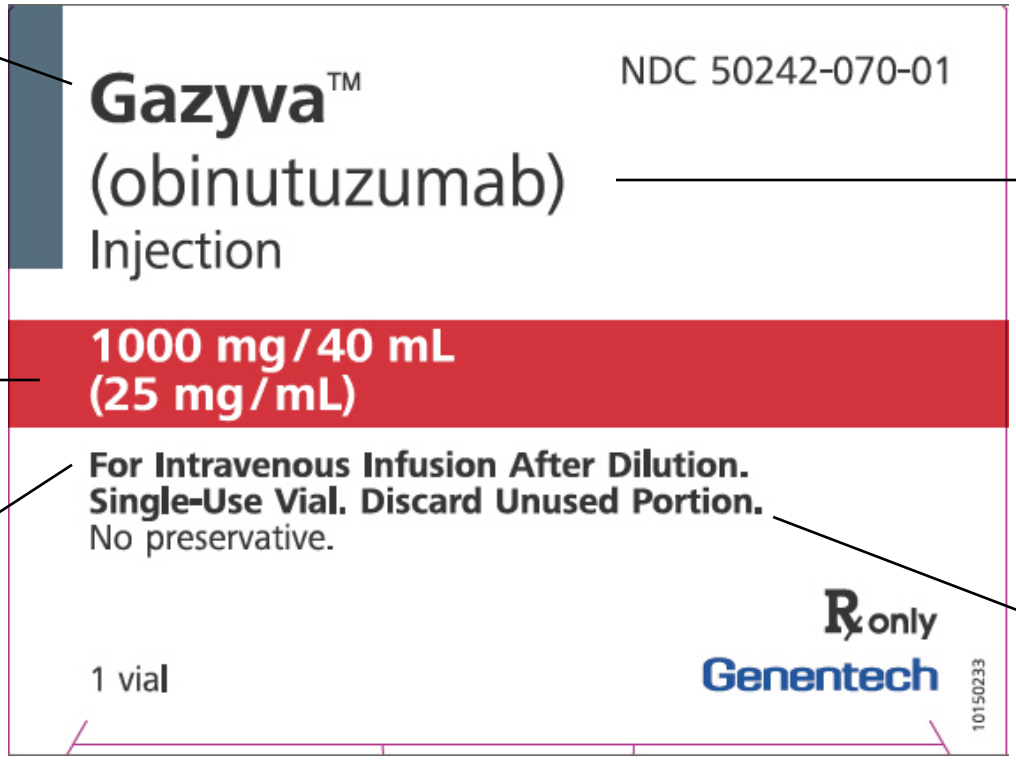
FDA U.S. FOOD & DRUG ADMINISTRATION

- Focuses on safety aspects of the container label and carton labeling design
- Released April 2013
- Accessible online at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf

General Considerations

- Considering end users and environments of use during drug development can allow identification of risks that can lead to error
- Sponsors should assess and minimize the risk for medication errors due to labels and labeling
- Develop drug products using analytical methods to investigate, understand, and correct identified risks

Critical Information on the Principal Display Panel (PDP)



Proprietary Name

Established Name or Proper Name

Product Strength

Route of Administration

Warning/ Cautionary Statements

Container Label Size: General Considerations

- Exemptions from some drug labeling requirements can be made under 21 CFR 201.10(i)
  - Proprietary name and established name (if any)
  - Product strength
  - Lot number
  - Name of manufacturer, packer, or distributor
- USP requires labels of official drug product to bear an expiration date

Container Label Size: General Considerations

- Situations where exemptions not available
  - Lack of space caused by failure to use all available space
  - Label space used for non-required information or other design-related elements (i.e. graphics/logos)

Text Size and Style: General Considerations

- Choose easy to read font, not lightweight or condensed
  - Improved readability with larger font size such as 12-point sans serif (e.g. Arial)
- 12-point font preferred when label size permits

Contrast of Text and Background: General Considerations

- Choose text and background color to afford adequate legibility of text
- Avoid color combinations that do not afford maximum legibility of text

Information Crowding/Visual Clutter: General Considerations

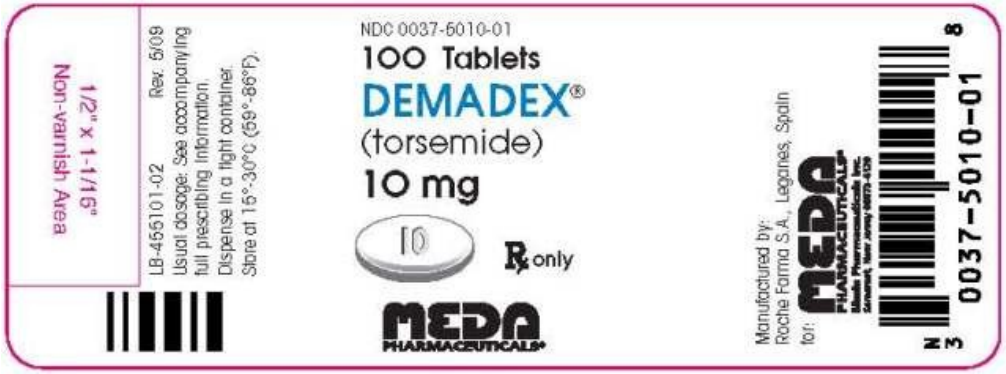
- Crowded labels may make important information difficult to read or easily overlooked
- Separate lines or blocks of text with sufficient white space
- Move less important information to back panels, side panels, or prescribing information

Information Crowding/Visual Clutter: General Considerations

- Avoid superimposing text over images or logos
- Logo immediately before or after the proprietary name can be misinterpreted as an additional letter in the proprietary name

Images of Tablets/Capsules: General Considerations

- Can help healthcare professionals confirm they are dispensing the correct medication
- Images should appear at bottom of labels and labeling
- Should not compete in size or prominence with proprietary name, established name, or strength
- Images should represent the actual tablet or capsule, reflecting true size, color, shape, and imprint.
- Do not recommend use of schematic or computer-generated images



Dangerous Abbreviations, Acronyms, and Symbols: General Considerations

- Certain abbreviations, acronyms, and symbols are dangerous and should not be used
  - Misinterpretations can lead to mistakes
- Non-standardized abbreviations, symbols, and dose designations can also lead to mistakes
- Refer to The Joint Commission's "Do Not Use" list
- Refer to the Institute for Safe Medication Practices (ISMP) "List of Error Prone Abbreviations, Symbols, and Dose Designations"

Typical Pharmacy Shelf

Look-alike Container Labels and Carton Labeling: General Considerations

- Encourage Sponsors to create labels and labeling sufficiently distinct from that of their other products
- Consider when products are customarily stored side-by-side or near one another

Look-alike Container Labels and Carton Labeling: General Considerations

Look-alike Container Labels and Carton Labeling: General Considerations

- Use color prudently to bring attention to important information (e.g. product name, strength, important warnings)
  - Consider variation in color perception
  - Do not want to encourage identification by color only since it may discourage reading of labels

Color Differentiation: General Considerations

- Can differentiate products within a manufacturer's product line
- Can differentiate strengths within a manufacturer's product line
- Can highlight certain aspects of the label, such as important warning statements

Color Coding: General Considerations

- Uses color to designate a specific meaning
- FDA generally recommends avoiding color coding in most instances
  - Reserved for special circumstances after human factors testing and feedback on the prototype from all end users is received and evaluated by FDA prior to use

Color Coding: General Considerations

- May actually increase error when color is relied upon as a shortcut to proper identification
- Color codes not always meaningful to end users outside the limited environment

Color Coding: General Considerations

- Certain applications of color coding are appropriate (e.g. warfarin)

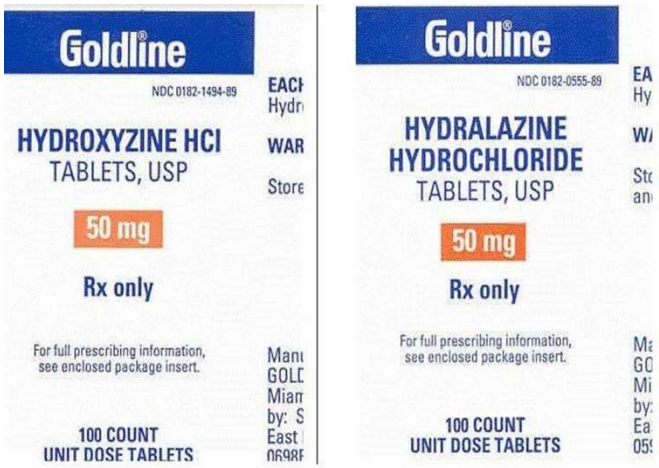
Color Coding: General Considerations

- Color coding can sometimes lead to confusion

Special Considerations for Proprietary, Established, and Proper Names

Tall Man Lettering

– Dissimilar letters are placed in upper case letters to bring attention to point of dissimilarity



HydrALAZINE
HydrOXYzine

Special Considerations for Product Strength

- Strength Differentiation: Make sure product strength stands out on the container label and carton labeling. Techniques include:
  - Boxing
  - Prominent typeface or type weight
  - Color differentiation

Special Considerations for Product Strength

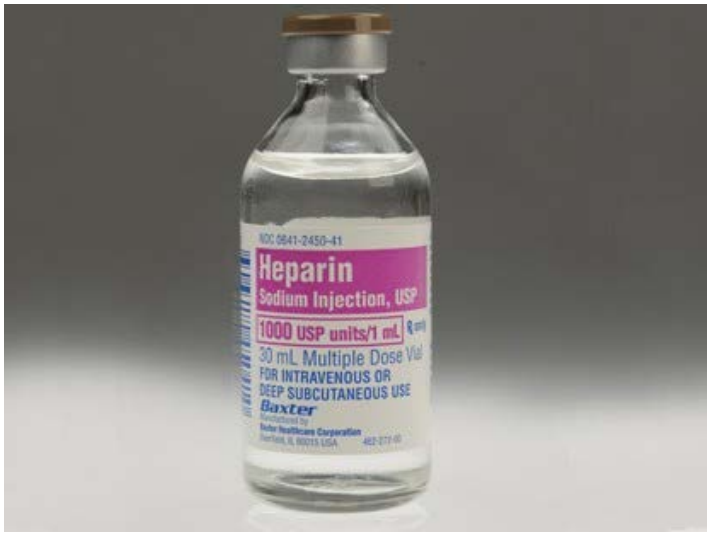
- Strength Designations should use a consistent unit of measure across all elements of labels and labeling

Dosing for Perioperative Hypotension

Intravenous bolus administration:
50 mcg to 250 mcg

Special Considerations for Product Strength

- Small Volume Parenteral Products
  - USP General Chapter <7> *Labeling*
    - Total quantity per total volume followed by concentration per milliliter (mL)



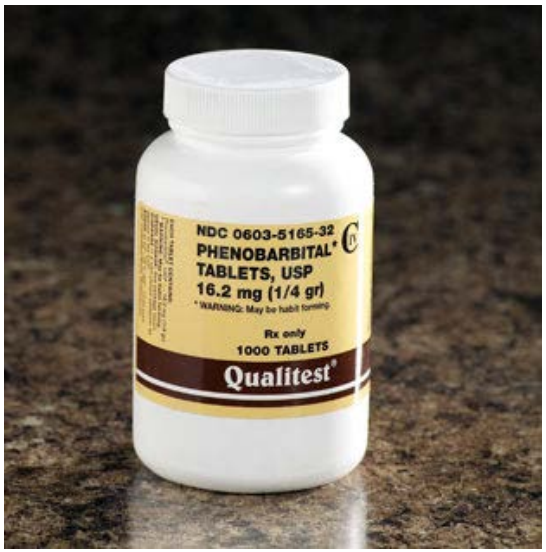
How many USP units are in this vial?

30,000 units

Special Considerations for Product Strength

- Metric Measurements
  - Dose or strength expression should appear in metric units of measure such as mL, mg, and mcg

1/4 gr?



Case Study: Using HFE to Redesign Container Labels and Carton Labeling

HFE & C/C Label Redesign

- Merck used the principles of Human Factors Engineering to redesign 34 of its drug container labels
  - The 16 solid oral drugs affected by the revisions include: Cozaar, Crixivan, Hyzaar, Isentress, Janumet, Januvia, Mevacor, Noroxin, Prinivil, Prinizide, Propecia, Proscar, Singulair, Zocor, and Zolinza.
  - About 60 labels in total underwent redesign
  - Usability Studies were conducted with pharmacists and pharmacy technicians to demonstrate that the labels improved the accuracy of dispensing within a pharmacy.

- FDA/CDER and Merck worked closely in the design of the HF usability studies and to ensure the labels meet regulatory standards.
  - Work with FDA/CDER began early in redesign, and extended over the course of several years
  - A number disciplines/offices in FDA involved in collaboration: OMP, OSE/DMEPA, ONDQA, OND

The redesigned c/c labels include an increased font size for the drug's proprietary and chemical names, the addition of a 3-D picture of the drug, more prominent positioning of the drug's expiration date and special coding for the pharmacist, and the addition of 2 color-coded bands on the bottles to denote brand and dosage strength

Previously Marketed Labels

Approved c/c Labels

Outcomes

- Merck's redesigned c/c labels approved in 2011
- FDA/CDER publically commended Merck's efforts recognizing that the project "… was no small undertaking, and we are hopeful that Merck's new standardized labels will aid in reducing pharmacy selection errors."

Questions

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