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DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance.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 301-796-6571.

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

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Drug Safety
Container label and package design safety

- Learning based on voluntary practitioner reporting
- FDA Adverse Event Reporting System (FAERS)
- ISMP National Medication Error Reporting Program (MERP)
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- Legible, readable, easy to understand
  - Container label size
  - Text size and style
  - Contrast of text and background colors
  - Crowding and visual clutter
  - Dangerous abbreviations, acronyms, symbols
Avoid look-alike container labels and cartons
  - Corporate trade dress
  - Use of color
- Routes of administration
- Warnings for critical information
- Expiration dates
- Bar codes and National Drug Code #s
- Controlled substance schedule (II-IV)
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- Product strength
  - Strength designation and differentiation
  - Small volume parenterals
  - Dry powder products
  - Salt nomenclature and pro-drugs
  - Metric measurement
  - Net quantity statement location
  - Leading and terminal zeros, decimals and commas (ratio expression – 1:1,000, etc.)
United States
2 tablets = 400 mg or 2 x 400 mg tablets?
TAMIFLU®
(oseltamivir phosphate) Capsules

75 mg

Each capsule contains oseltamivir phosphate equivalent to 75 mg oseltamivir (free base).

10 Capsules

Rx only.

To Open Lift This Flap
Before

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

- Unit dose blisters
  - Cell labels, strength, label design, etc.
- Ferrules and cap overseals
- Color closure system for KCl injection
- Large volume parenteral labels
- Pharmacy bulk packages
- Dosing devices
- Drug samples packaging
USA