



# Container label and package design safety

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## 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*DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.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be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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

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# Container label and package design safety

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- Learning based on voluntary practitioner reporting
- FDA Adverse Event Reporting System (FAERS)
- ISMP National Medication Error Reporting Program (MERP)



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

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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

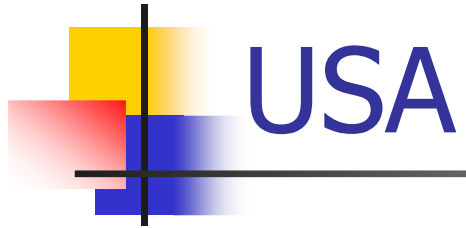


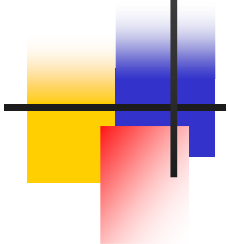
## Guidance for Industry

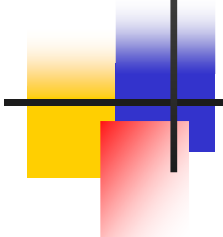
### Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

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- 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)









## Guidance for Industry

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

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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?





NDC 0004-0800-85



# TAMIFLU<sup>®</sup>

(oseltamivir phosphate) Capsules

## 75 mg

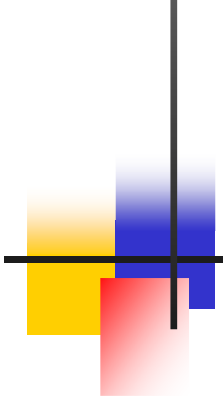
Each capsule contains oseltamivir phosphate equivalent to 75 mg oseltamivir (free base).

### 10 Capsules



**R<sub>x</sub> only.**

To Open Lift This Flap



NDC 0054-0352-44 30 mL

**MORPHINE SULFATE**  
Oral Solution (II)

**20 mg/mL**

ONLY FOR USE IN PATIENTS WHO ARE OPIOID TOLERANT

SUGAR AND ALCOHOL FREE.

Rx only

[Redacted]

Before

NDC 0054-0352-50 120 mL

**MORPHINE SULFATE**  
Oral Solution (II)

**100 mg per 5 mL  
(20 mg/mL)**

ONLY FOR USE IN PATIENTS WHO ARE OPIOID TOLERANT

PHARMACIST: Must dispense the enclosed Medication Guide to each patient.

[Redacted] . Sugar and Alcohol Free.

[Redacted] \$ Rx only

After



## Guidance for Industry

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

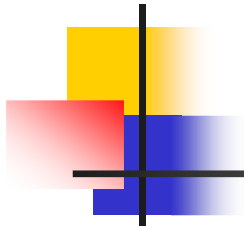
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- Unit dose blisters
  - Cell labels, strength, label design, etc.
- Ferrules and cap overseals
- Color closure system for KCl injection
- Large volume parenteral labels
- Pharmacy bulk packages
- Dosing devices
- Drug samples packaging

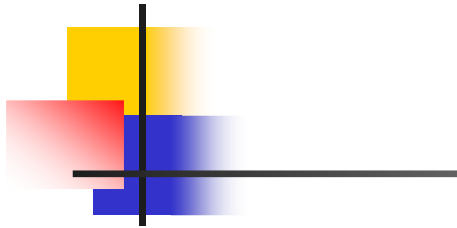


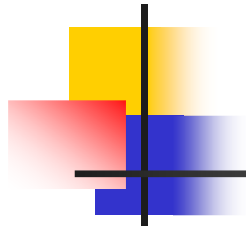
# USA

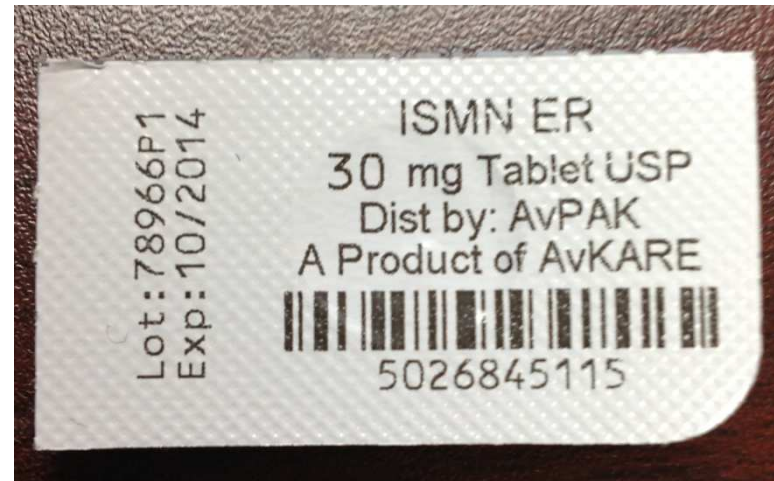
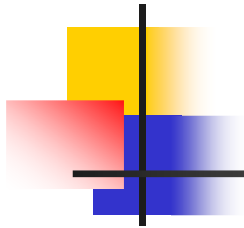


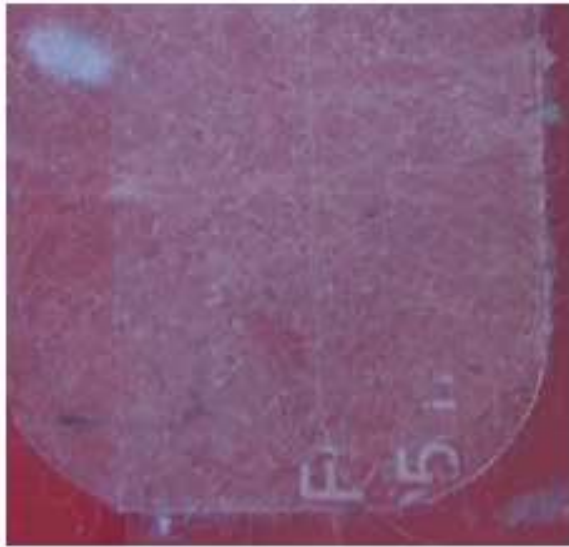




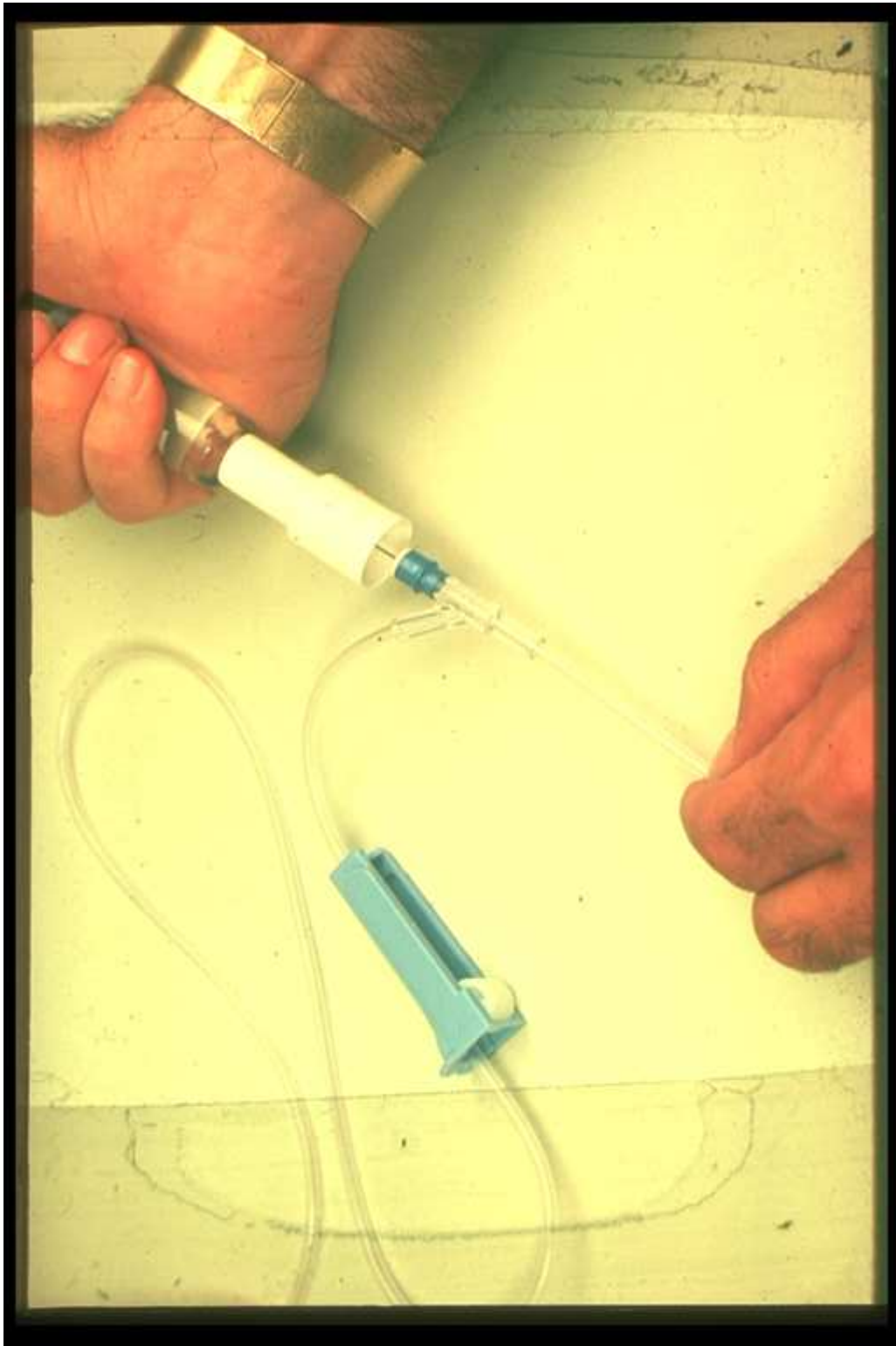


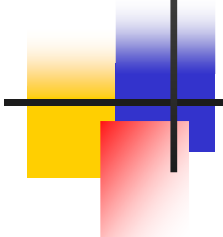












<p>NDC 61314-227-05 Rx Only</p> <p><b>FALCON</b> PHARMACEUTICALS</p> <p><b>Timolol Maleate Ophthalmic Solution USP</b> <small>Equivalent to Timolol Maleate 5.8mg/mL</small></p> <p><b>0.5%</b></p> <p>5 mL STERILE</p> <p>AFFILIATE OF <b>ALCON</b> LABORATORIES, INC.</p>	<p>NDC 61314-245-01 Rx Only</p> <p><b>FALCON</b> PHARMACEUTICALS</p> <p><b>Betaxolol HCl Ophthalmic Solution</b> 0.5% as base</p> <p><b>0.5%</b></p> <p>5 mL STERILE</p> <p>AFFILIATE OF <b>ALCON</b> LABORATORIES, INC.</p>	<p>NDC 61314-229-05 Rx Only</p> <p><b>FALCON</b> PHARMACEUTICALS</p> <p><b>Levobunolol Hydrochloride Ophthalmic Solution USP</b></p> <p><b>0.5%</b></p> <p>5 mL STERILE</p> <p>AFFILIATE OF <b>ALCON</b> LABORATORIES, INC.</p>
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**Adrenalin® Chloride Solution**  
(Epinephrine Nasal Solution, USP)

N 0071-3003-13

**1 mg per mL**  
Vasoconstrictor  
**For Topical Application**

1:1000

1 fl oz (30 mL)

PARKE-DAVIS

**Adrenalin® Chloride Solution**  
(Epinephrine Nasal Solution, USP)

N 0071-3003-13

**1 mg per mL**  
Vasoconstrictor  
**For Topical Application**

1:1000

1 fl oz (30 mL)

PARKE-DAVIS

**Adrenalin® Chloride Solution**  
(Epinephrine Injection, USP)

N 0071-4011-13

**1 mg per mL**  
**For Hypodermic Use**

1:1000

30 mL

PARKE-DAVIS

**Adrenalin® Chloride Solution**  
(Epinephrine Injection, USP)

N 0071-4011-13

**1 mg per mL**  
**For hypodermic use**

1:1000

30 mL

PARKE-DAVIS





**ACETYL CYSTEINE**  
SOLUTION, USP  
20% (200 mg/ml)

For Inhalation  
Oral Administration (Acetaminophen Analgesic)  
**NOT FOR INJECTION**

**30 mL** VIAL  
PRESERVATIVE FREE

AMERICAN  
RECENT  
LABORATORIES  
INC. PHILLY, PA 19104