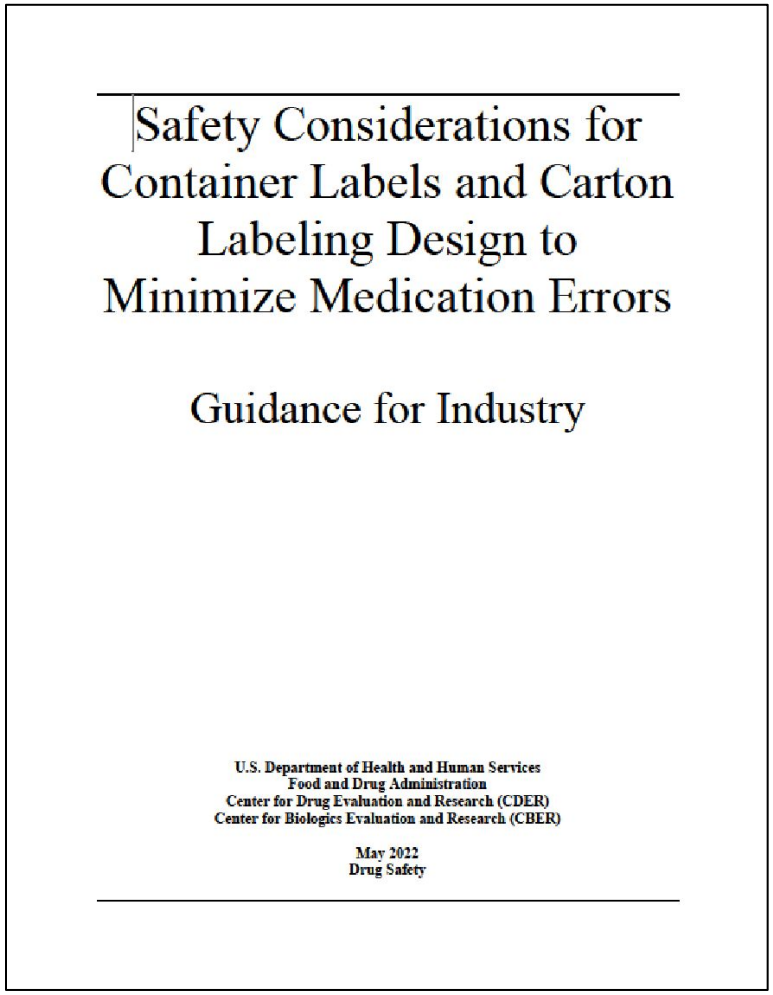
Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

FDA Guidance for Industry

Frestedt Incorporated Review

25MAY2022

Reference and Disclaimer



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

Guidance for Industry

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

May 2022
Drug Safety

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize-medication-errors?utm_medium=email&utm_source=govdelivery

Disclaimer: this slide deck is not intended to replace a careful reading of the US FDA Guidance for Industry and this slide deck does not constitute regulatory guidance without further discussion.

- Division of Medication Error Prevention and Analysis in the Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER) at the FDA
- Released: MAY2022

Applies to:

- **Prescription drugs** (new or abbreviated drug applications) with approvals
- **Prescription drugs** without approved application
- **Biological products** with approved biologics application

Medication Error Prevalence

33% related to labeling or packaging issues and make-up

30% medication error fatalities (Aspden 2006)

Aspden, P, Wolcott, J. A., Bootman, J.L., and Cronenwett, L. R., eds., Preventing medication Errors, IOM, Washington, DC: The National Acedemies Press, 2006, p. 275

Frestedt incorporated

Applicable Regulations

Federal Food, Drug and Cosmetic Act 21 U.S.C 301 et seq.

https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act

21 CFR part 201 (drugs)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=201&showFR=1

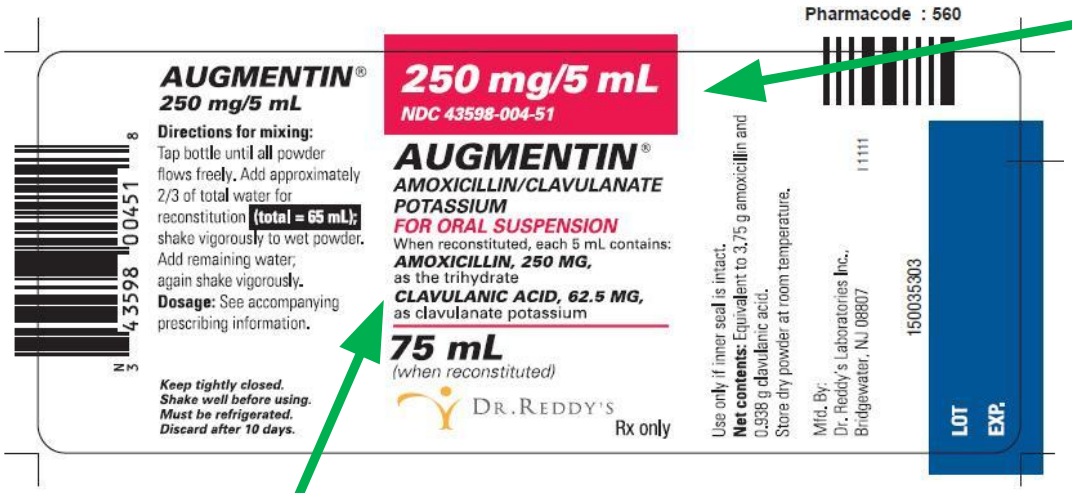
21 CFR part 610, Subpart G (biological products)

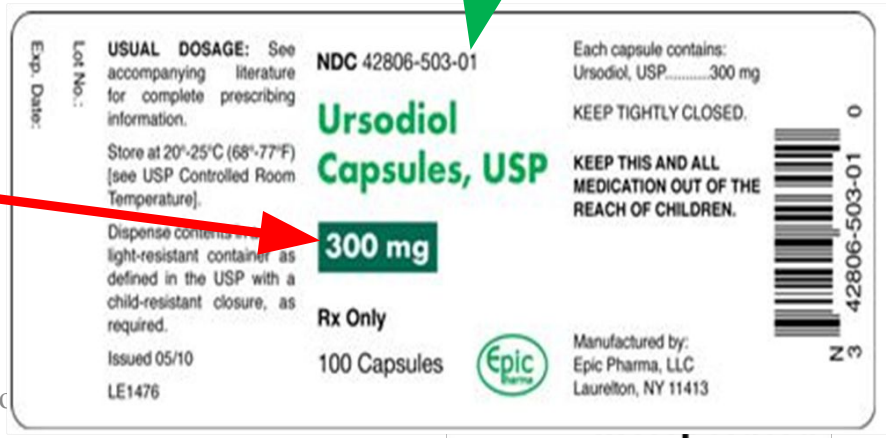
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=610

Principal Display Panel Requirements

- **Name**/proper name
- **Dose** (e.g., 2 tablets, 20 units)
- **Strength** (e.g., milligrams, mg/mL)
- **Route**(s) of administration (e.g., oral, IM, IV, topical)
- **Warnings/cautionary statements** (if applicable)
- Controlled substance **schedule** (if controlled)
- **Expiration** date
- **Frequency** (if space available)

Display Panel Examples





Strong contrast

Adequate contrast

Clear reconstitute dosing

Dose?
Route?
Strength ✓

Poor Design Examples

- Product name, dose, strength missing, confusing or not prominently located
- Cluttered by extraneous information, graphics.
- Size, style, color contrast/design elements

Poor Design Examples Continued

- Key information is not in same field of vision (e.g., user has to rotate container)
- Similar appearances between products or strengths
- Overlapping text on both sides of transparent container (e.g., vials)

End User Perspectives

Acute care

https://school.wakehealth.edu/research/institutes-and-centers/center-for-healthcare-innovation/research/med-safe

Crash cart medication drawer

https://health.ucdavis.edu/cppn/resources/clinical_skills_refresher/crash_cart/top_drawer.html

Legible, Readable, Understandable

Product naming, labeling, packaging should be aimed at the *end user*

- Considering: intended **uses**, end **users**, **environment** of use

Labels and Containers:

2. Wording oriented in same direction
3. Placed in same field of vision
4. Sufficient blank space for readability

Examples of Label Details

- Label cannot cover packaging so that inspection of contents is not possible (if applicable)
- Text size such as 12-pt sans serif (e.g., Arial)
- Non-critical information on side or back panel
- Image of product at bottom of label

Examples of Label Details Continued

- Avoid abbreviations (e.g., *IU* is close to route *IV*)
- Differentiate product colors (avoid color coding)
- Packaging and labeling language/content consistency
- Tall Man lettering (e.g., drugOXide versus drgEXide)
- Strength clarification (*100 mg per tablet* rather than *100 mg)*

Examples of Label Details Continued

- Avoid use of word “NOT” *(*e.g., for use in ears only)
- Neuromuscular blocking agents special (WARNING: Paralyzing Agent in red, bold required)
- Barcodes visible on label (FD&C Act (21 U.S.C 321 (k))
- Transferable or peel-off labels for injections (once drawn)

We Can Help

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REGULATORY LABELING REVIEWS

Frestedt Experience

Labeling Projects

Frestedt Incorporated has supported dozens of client-specific medical device, pharmaceutical and food labeling projects. The Frestedt team uses proprietary preparation methods with a proven track record for delivering labeling and translations in compliance with US Food and Drug Administration (FDA) as well as international regulatory requirements and standards.

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