Update on Proposed General Chapter <7> Labeling

*Impact on General Notices*

**Donna Bohannon, R. Ph., CPPS**
Scientific Liaison
Nomenclature, Safety and Labeling Expert Committee
General Chapter <7> Labeling Rationale

New additions

What will be official soon in the general chapter?

Heparin label changes

Single-dose container definition
Background

- Drugs recognized in USP–NF must be packaged and labeled in compliance with compendial standards (FDCA 502(g)).
- Standards for an article recognized in USP compendium are expressed in monographs, general chapters, general notices (Section 10)

Purpose

- To compile all general labeling requirements into one general chapter
General Notices provides the basic assumptions and definitions for applying USP-NF compendial standards, which are applied to official articles recognized in monographs and any applicable general chapters.

General Chapters contain requirements applicable to monographs to which they apply. General Chapter requirements supersede General Notice requirements in case of conflict.

Monograph requirements are specific to the monograph in which they appear. Monograph requirements supersede General Notice and General Chapter requirements in case of conflict.
General Notices 10.0  Deconstruction

GN 10.0
Preservation, Packaging, Storage and Labeling

GC<659>
Packaging and Storage

10.10 – 10.30.100
10.30

GC<7>
Labeling

10.40 – 10.40.100.1
10.20 – 10.30*

* Includes labeling only.
General Chapter <7> Composition

GN
General Notices

<1>
Injections

<17>
Prescription Container Labeling

<7>
Labeling

Public comments led to further revision

Coordinated with revisions to General Chapters <1>, <659> and General Notices

To be published in PF 39(6) Nov/Dec 2013

– Public comment Nov 1, 2013 to Jan 31, 2014
Labeling Definition
Labels and Labeling for Injectable Drug Products
Labels and Labeling for Other Drug Products and Categories
General Labeling
Labeling Definition

- **Label** – immediate container
- **Labeling** - immediate container or on or in any package or wrapper in which it is enclosed, except any outer shipping container.
- Minimum requirements for product identification
- Subject to more comprehensive requirements.
Strength and Total Volume for Single and Multiple-Dose injectable drug products

Local Anesthetic and Epinephrine injections

Ratio Expression

Pharmacy Bulk Package

Ferrules and Cap Overseals

Potassium Chloride for Injection Concentrate

Neuromuscular Blocking and Paralyzing Agents

Aluminum in Large volume injections, Small injections and Pharmacy bulk Packages used in Parenteral Nutrition Therapy
Proposed General Chapter <7> Labeling

- Single entity drug products that can also be expressed as a ratio such as epinephrine shall be labeled only in terms of strength per mL.
  - Ratio expression such as 1:1000 is an unacceptable format for single entity drug products.
Strength and Total Volume for Single and Multiple-Dose injectable drug products

Local Anesthetic and Epinephrine injections

Ratio Expression

Pharmacy Bulk Package

Ferrules and Cap Overseals

Potassium Chloride for Injection Concentrate

Neuromuscular Blocking and Paralyzing Agents

Aluminum in Large volume injections, Small injections and Pharmacy bulk Packages used in Parenteral Nutrition Therapy
Ferrules and Cap overseas

- Official December 1, 2013

- May only contain cautionary statement

- When no cautionary statement is necessary, the top surface of the vial, including the ferrule and cap overseal must remain blank

Figure A: Ferrule with warning language
Strength and Total Volume for Single and Multiple-Dose injectable drug products

Local Anesthetic and Epinephrine injections

Ratio Expression

Pharmacy Bulk Package

Ferrules and Cap Overseals

Potassium Chloride for Injection Concentrate

Neuromuscular Blocking and Paralyzing Agents

Aluminum in Large volume injections, Small injections and Pharmacy bulk Packages used in Parenteral Nutrition Therapy
Labels and Labeling for Other Drug Products and Categories

- Amount of Ingredient per dosage unit
- Expiration and Beyond-Use Date
- Compounded Preparations
- Use of Leading and Terminal Zeros
- Alcohol
- Botanicals
- Electrolytes
- Injectable and Topical
- Salts of Drugs
- Special Capsules and Tablets
- Products that contain vitamins
- Controlled room temperature
- Light resistant container
- Single-unit container
- Repackaged Single-unit container
- Single–Dose Container
- Unit of use Container
- Protection from Freezing
- Prescription Container Labeling
The label on the container package of an official compounded preparation shall include the word “compounded” after the drug name.

Additionally, USP official compounded preparations for animal patients will include the word “veterinary” following the full official name.

Add the following:

- Enalapril Maleate Compounded Oral Suspension, Veterinary

**DEFINITION**

Enalapril Maleate Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled content of enalapril maleate (C₂₀H₂₈N₂O₅·C₄H₄O₄).

Prepare Enalapril Maleate Compounded Oral Suspension, Veterinary 10 mg/mL as follows (see Pharmaceutical Compounding—Nonsterile).
A single-dose container is a container of sterile medication for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing criteria.

[ NOTE— For this definition only, container is synonymous with packaging system and container–closure system.]

A single-dose container is designed for use with a single patient as a single injection/infusion. A single-dose container is labeled as such and, when space permits, should include on the label appropriate discard instructions. Examples of single-dose containers are vials, ampuls, and prefilled syringes.

1 Exceptions may be considered only under conditions described in USP Pharmaceutical Compounding—Sterile Preparations <797>

Comment periods ends September 30, 2013
At a minimum, a prescription container shall be labeled in a **patient-centered manner.** The label shall contain **essential information** that is important for the patient’s safe and effective use of the medicine. Labels should be designed and formatted to **improve readability and understanding.**

See <17> *Prescription Container Labeling*
Users are reminded to always refer to the *General Notices* in assessing or applying any compendial standards. With regard to labeling, for example, the *General Notices* addresses a number of labeling-related aspects, among them:

- **3.20 “Indicating Conformance”** (when an article may be labeled *USP, NF*, or *USP–NF*, and requirements related to differences in identity, strength, quality, or purity)
- **5.20.10 “Added Substances, Excipients, and Ingredients in Official Substances”**
- **6.70 “Reagents”**
- **8.240 “Weights and Measures”** (e.g., microgram may be represented as either µg or mcg. For labeling or prescribing purposes, “mcg” is preferred).
Heparin Labeling Changes

Posted: 21-Nov-2012

1. Why is the labeling section of the USP Heparin Lock Flush Solution and USP Heparin Sodium Injection monographs being changed?

2. How are the labels for USP Heparin Lock Flush Solution and USP Heparin Sodium Injection monographs being changed?

3. When will this change occur?

4. How will USP communicate this change to stakeholders?

5. What will the labels look like?

6. Where is information about labeling located in the USP?

7. How will this change affect my practice?

8. What do I need to know as a manufacturer?

The specific wording in the labeling regarding strength and volume for Heparin Sodium Injection and Heparin Lock Flush Solution will be removed from the monographs. In lieu of these specific requirements, the manufacturer must adhere to the labeling standard in the General Chapter <1> Injections related to strength and volume expression for injections. The change will become official on May 1, 2013, at which time, all drug products affected by this change need to be in compliance with the standard.

9. Does the labeling change affect all types of heparin products?

The labeling change affects Heparin Sodium Injection and Heparin Lock Flush Solution monographs.
Heparin Labeling Changes

- Conforms with standards regarding Strength and Total Volume for Single- and Multiple-Dose Injectable Drug Products

- Official May 1, 2013
Questions
Thank You