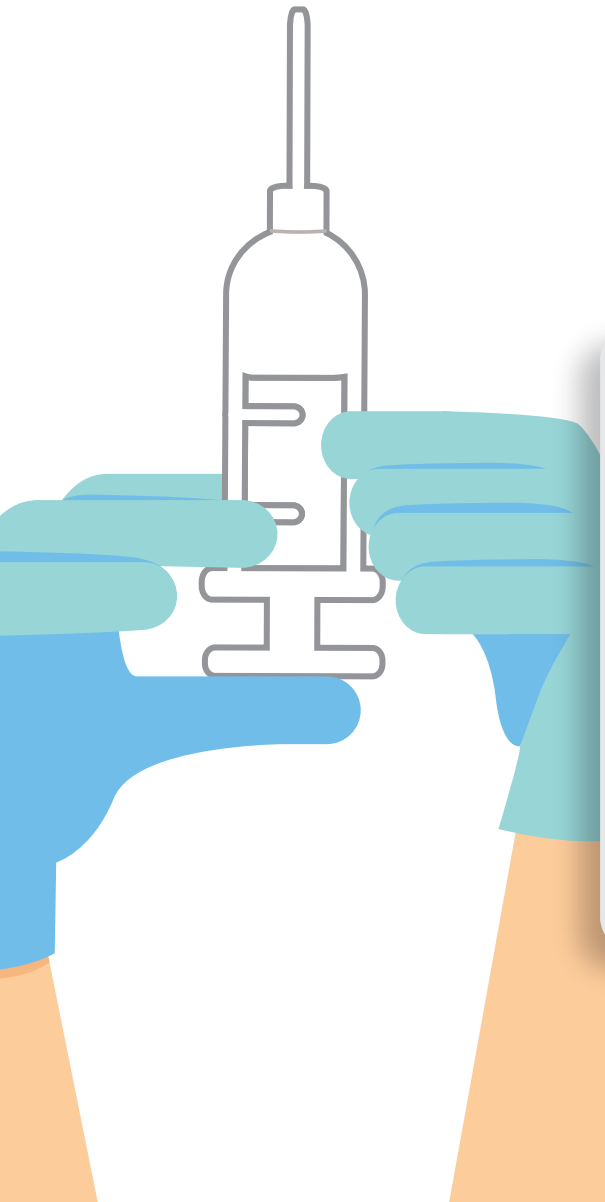
IMPORTANT LABELING CHANGES
TO **CRITICAL CARE** MEDICATIONS

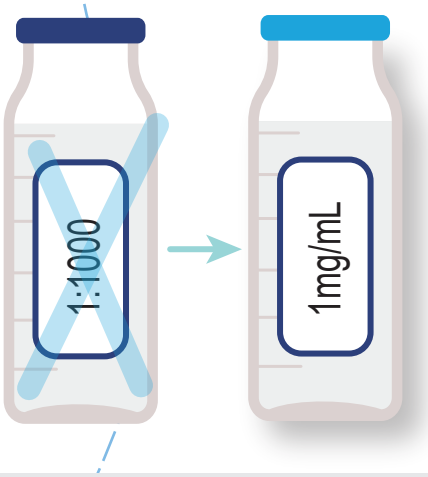
What are the changes?

The FDA is requiring removal of ratio expressions of strength from the drug labeling of single-entity injectable drug products (i.e., drug products that contain only one active ingredient). Strength will be expressed only as the amount per unit of volume (i.e., mg/mL).

This revision affects Epinephrine Injection, Isoproterenol Hydrochloride Injection, and Neostigmine Methylsulfate Injection.



ESTABLISHED NAME	RATIO	AMOUNT PER UNIT OF VOLUME
Epinephrine Injection, USP	1:1,000 1:10,000	1 mg/mL 0.1 mg/mL
Isoproterenol Hydrochloride Injection, USP	1:5,000	0.2 mg/mL
Neostigmine Methylsulfate Injection, USP	1:1,000 1:2,000	1 mg/mL 0.5 mg/mL

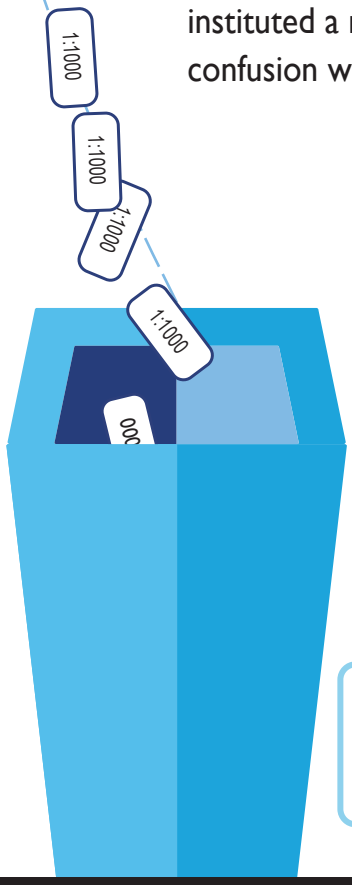


When will health care providers start seeing the changes?

You may already be seeing the revised drug labeling in the marketplace. The FDA continues to work with some manufacturers on these revisions to the epinephrine injection labeling.

Why are we requiring the changes?

The FDA is requiring the changes to help prevent medication errors related to strength being expressed as a ratio on labeling. There have been several reports of medication errors indicating that ratio expressions are confusing to healthcare providers and contributed to the errors. Some of the medication errors resulted in serious adverse outcomes, including death. The United States Pharmacopeia (USP) instituted a new labeling standard in an effort to reduce medication errors related to confusion with ratio expressions.



How will the changes affect health care providers?

Health care providers should start prescribing, communicating, dispensing, and labeling these drugs in mg/mL rather than ratios. Health care facilities should review systems and processes to ensure order sets, protocols, references, dispensing labels and labels for drug storage bins are updated to reflect this change.

Report a Problem to MedWatch

The FDA Safety Information and Adverse Event Reporting Program

For more information please visit:
www.fda.gov

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