

Appendix. Recommendations from the 2011 FDA Voluntary Guidance and 2009 CHPA Voluntary Guideline Categorized as Top Tier – Rationale, Examples, and Magnitude of Potential Overdose^a

Recommendation	Rationale	Example	Magnitude of Potential Overdose
Dosing devices should be included with all products	A dosing device with incorrect or un-calibrated volumetric units may be used	A kitchen tablespoon is used to dose medication rather than a teaspoon	3-fold
Atypical units should not be used (e.g., drams, dropperfuls)	If non-standard units are used, a more familiar unit may be assumed	1 teaspoon of infant acetaminophen is given rather than 1 “dropperful” ^b	3-fold
Do not use teaspoon and tablespoon units together	Teaspoon and tablespoon units may be confused when using a device or directions with both	1 tablespoon of medication is given rather than 1 teaspoon	3-fold
Do not use trailing zeros (eg., do not use 1.0; use 1)	The decimal may be overlooked	10 mL of medication is given rather than 1 mL	10-fold
Always use leading zeros (e.g., use 0.5; do not use .5)	The decimal may be overlooked	5 mL of medication is given rather than 0.5 mL	10-fold
Use small font used for numerals in fractions (e.g., “½” instead of “1/2”)	Dosing directions with fractions with numerals in the same size font with a “/” may be interpreted to mean give either the first “or” second amount	2 teaspoons of medication is given rather than ½ teaspoon	4-fold
Do not use extraneous units on the dosing device that do not correspond to units in the directions	A dose may be inadvertently measured using the extraneous units, which appear on the device	2 teaspoons of medication are given rather than 2 mL as the dosing device has extraneous teaspoon units	5-fold
Dosing devices should not be “significantly larger” than largest recommended dose	A completely full dosing device may be assumed to be the largest recommended dose	30 mL of medication is given rather than the largest recommended dose of 10 mL because a dosing cup is filled to the rim	3-fold
All doses from directions should be marked on dosing device	A completely full dosing device may be assumed to be the appropriate dose if the specific numeric dose is not marked on the device	30 mL of medication is given rather than the recommended dose of 7.5 mL as 7.5 mL is not marked and dosing cup is filled to the rim	4-fold

^a Top Tier recommendations are those that directly address potential ≥3-fold dosing errors. "Guidance for Industry: Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products", US Food and Drug Administration (FDA), May 2011 and "Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age", Consumer Healthcare Products Association (CHPA), November 2009.

^b Concentrated infant acetaminophen is no longer commonly available, but before 2012, concentrated infant acetaminophen product often contained a dosing dropper with a largest marked dose of 1.6 mL