

Guideline Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age

1. Introduction

As part of multiple stakeholder efforts to help prevent accidental, unsupervised medication ingestions and overdoses in children, this document suggests ways to improve the consistency and standard format of volumetric measures within the dosing directions on the outer packaging and immediate container label, as well as on the dosing device for OTC oral liquid drug products with dosing directions for children, defined as ≤12 years of age (both covered under the monograph system as well as an approved NDA/ANDA). While research evidence is limited, the recommendations made herein do represent the integration of stakeholder communications and standards, including those from authoritative bodies and professional organizations, as well as knowledge gained from consumer experience and research with OTC medicine products.

Although similar principles may apply, this does not address other oral liquid medicines such as those for only adults, prescription medicines or dietary supplements whose special packaging may require additional considerations. Neither does this document address the packaging nor directions for products with children's dosing intended for topical use such as crèmes, pastes or sprays.

2. Background

One of the principle objectives of OTC Drug Facts Labeling regulation was to establish a standardized format and content of certain OTC labeling information so as to assist consumers in reading and understanding the OTC labeling. While the OTC Drug Facts regulation lays out specific labeling format and content information which is required for the ingredients, uses, warnings, directions and other information, the OTC Drug Facts regulation does not specify standard dose-related volumetric measures.

Communications exist for parents and caregivers about the best ways to give medicines to children, especially the proper use of oral liquid medicines (1,2,3,4,5). Key points to parents and caregivers are to always read the label carefully, use the dosing device that comes with the product and to understand the types of liquid measure units for dosing liquid medicines. Some have suggested preferred volumetric measure terms, units and abbreviations, as well as potential areas to avoid (6,7,8,9,10,11,12).

Findings from an industry-wide survey (April 2009) of OTC oral liquid drug products with dosing directions for children suggest potential areas to improve the consistency and standard format of volumetric measures:

- Dosing Directions
 - Representation in a dosing chart versus running text
 - Volumetric measures: unit types and standards; abbreviations, formats and style
 - Decimals and fractions

- Dosing device accompanying the product; consistency with labeling dosing directions

3. Proposal Objectives

To identify and support consistent terminology, format, and text for volumetric measures within the context of OTC Drug Facts dosing directions for OTC oral liquid drug products with dosing directions for children.

4. Proposal

The following recommendations are suggested for the labeling dosing directions on the outer packaging and immediate container label, as well as on the dosing device for OTC oral liquid drug products with dosing directions for children (includes products marketed under the OTC monograph system and those marketed under an approved NDA/ANDA).

4.1 OTC Drug Facts Dosing Directions: Outer Package and Immediate Container Labeling

A. Dosing Directions: Statement(s)

1. Provide a statement(s) that 1) encourages a consumer to select the right dose, 2) use the dosing device that accompanies the product, 3) keep dosing device with product/do not discard dosing device (see Appendix for examples of possible statements)
2. Provide a definition of any volumetric unit of measure specified in the product's dosing directions using the following abbreviations and full text exactly:
 - "mL = milliliter"
 - "tsp = teaspoonful"

B. Dosing Directions: Guidelines for Volumetric Measures

1. If space permits, use a dosing table format to provide dosing directions
2. Use milliliter as the preferred unit of measure in the dosing directions
 - use a milliliter unit alone (e.g., "5 milliliter or 5 mL")
 - or, alternatively, use a milliliter unit together with a "teaspoonful" unit equivalent (e.g., 5 mL (1 tsp))
3. Avoid use of a "teaspoonful" unit alone
4. Use the following abbreviation and text exactly:
 - Abbreviations: "mL"; "tsp" (preferable to use only one unit of measure)
 - Full text: "teaspoonful"
5. Avoid use within labeling dosing directions of the following: tablespoon, cubic centimeters, cc, dram, fluid ounce, Fl. Oz., and dropper(ful).
6. Use a format and style for expressing fractions that is consistent with the type of measure unit (i.e., metric or English/Imperial)

- for metric units, use a decimal; if <1 mL volume, use decimal with a leading zero (e.g., 0.5).
- for English/Imperial units (i.e., teaspoonful), use a mathematical notation (e.g., lower case ½, but not upper case 1/2).

4.2 Dosing Device Accompanying the Product

A. Guidelines for Volumetric Measures

1. Provide a calibrated dosing device with all products
2. Provide graduated markings on the dosing device that include dosage(s) specified in the dosing directions
3. Use only the volumetric unit(s) of measure provided in the dosing directions; if using abbreviations, define abbreviations in the labeling dosing directions
4. Use contrasting graduated markings (e.g., etched or printed) so as to aid the readability of the measured liquid
5. Use only the fraction format and style (i.e., decimal or mathematical) provided in the dosing directions

5. Appendix: Examples

5.1 Examples: Dosing Directions Statement(s)

Example A:

“Measure the dose correctly using the enclosed [insert specific name of product’s dosing device, e.g., dosing cup, dropper, oral syringe] ”

“For accurate dosing, use the enclosed [insert specific name of product’s dosing device, e.g., dosing cup, dropper, oral syringe] to measure a dose”

Example C: Label statement using only mL (infant acetaminophen drops)

“Find right dose on chart below”

“Use only enclosed [insert specific name of product’s dosing device, e.g. dosing cup, dropper, oral syringe] designed for use with this product. Do not use any other dosing device.”

5.2 Examples: OTC Drug Facts Directions

Example A

Drug Facts	
Directions	
<ul style="list-style-type: none"> ■ for accurate dosing, use the enclosed [insert specific name of product's dosing device, e.g. dosing cup, dropper, oral syringe] to measure a dose ■ mL = milliliter; tsp = teaspoon 	
adults and children 6 years and over	10 mL (2 tsp) once daily; do not take more than 10 mL (2 tsp) in 24 hours.
adults 65 years and over	5 mL (1 tsp) once daily; do not take more than 5 mL (1 tsp) in 24 hours.
children 2 to under 6 years of age	2.5 mL (½ tsp) once daily. do not give more than 2.5 mL (½ tsp) in 24 hours.
children under 2 years of age	do not use

Example B

Drug Facts	
Directions	
<ul style="list-style-type: none"> ■ shake well before using ■ use only enclosed dosing device ■ mL = milliliter; tsp = teaspoon 	
adults and children 6 years and over	30 mL (6 tsp) once daily; do not take more than 30 mL (6 tsp) in 24 hours.
adults 65 years and over	15 mL (3 tsp) once daily; do not take more than 15 mL (3 tsp) in 24 hours.
children 2 to under 6 years of age	7.5 mL (1 ½ tsp) once daily. do not give more than 7.5 mL (1 ½ tsp) in 24 hours.
children under 2 years of age	do not use

Example C

Drug Facts		
Directions		
<ul style="list-style-type: none"> ▪ shake well before using ▪ use only with enclosed dosing device ▪ find right dose on chart below. If possible, use weight to dose; otherwise, use age. ▪ fill to dose level ▪ dispense liquid slowly into child's mouth, toward inner cheek ▪ if needed, repeat dose every 4 hours ▪ do not use more than 5 times in 24 hours ▪ use dropper to close bottle and maintain child resistance 		
Weight (lb)	Age (yr)	Dose (mL)
Under 24	Under 2	Call a doctor
24-35	2-3	1.6 mL (0.8 + 0.8 mL)
Attention: specifically designed for use with enclosed dosing device. Do not use any other dosing device with this product.		

¹ United States Food and Drug Administration. Medicines in My Home. URL: <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm093965.pdf>

² American Academy of Pediatrics. What is the best way to give my child medicine? URL: http://www.aap.org/publiced/BR_Medicine.htm

³ FamilyDoctor.Org. OTC Drugs: Special Groups at Risk of Adverse Effects. URL: <http://familydoctor.org/online/famdocen/home/otc-center/basics/853.html>

⁴ United States Food and Drug Administration. Giving Medication to Children: Q&A with Dianne Murphy, M.D. URL:

<http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM164439.pdf>

⁵ Consumer Products Healthcare Products. Treat with care – Kids and OTC cough and cold medicines.

<http://www.otcsafety.org/Media/128696932677584054.pdf>

⁶ United States Pharmacopeia. USP Quality Review. July 2004; No.80. URL:

<http://www.usp.org/pdf/EN/patientSafety/qr802004-07-01.pdf>

⁷ Institute for Safe Medication Practices. List of Error-Prone Abbreviations, Symbols, and Dose Designations. 2007. URL: <http://www.ismp.org/Tools/errorproneabbreviations.pdf>

⁸ USP-NF Online – 8.240. Weights and Measures and 1221 General Information

⁹ FDA Consumer Magazine. Avoiding Problems: Liquid Medicines and Dosing Devices. October 1994

¹⁰ Litovitz T. Implication of Dispensing Cups in Dosing Errors and Pediatric Poisonings: a report from AAPCC. Annals of Pharmacotherapy 1992;26;917-18.

¹¹ FDA Guidance for Industry Labeling OTC Human Drug Products — Questions and Answers. December

2008 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078792.pdf>

¹² Federal register 21 CFR 201. FDA Over-The-Counter Human Drugs; Labeling Requirements. Final Rule. March 17, 1999 64:51. Example 2 and 3. Pg 13298 and 13299.

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/UCM106781.pdf>

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