

FDA PRESS RELEASE

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For Immediate Release: May 4, 2011

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FDA issues final guidance for liquid OTC drug products with dispensing devices
Goal is to avoid accidental overdose

The U.S. Food and Drug Administration today released its final guidance to firms that manufacture, market, or distribute over-the-counter (OTC) liquid drug products packaged with cups, droppers, syringes, and spoons to measure and dispense the doses of medication.

The guidance, titled Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products, describes how easy-to-use dosage delivery devices and devices that minimize the risk of unintentional overdose can be provided for OTC medicines such as liquid pain relievers, cold medicine, cough syrups, and digestion aids.

"Accidental medication overdose in young children is an increasingly common, but preventable public health problem," said Karen Weiss, M.D., program director for the Center for Drug Evaluation and Research's Safe Use Initiative.

The FDA issued the guidance because of ongoing concerns about the potential accidental drug overdoses that can result from the use of dosage delivery devices with markings that are confusing, unclear or inconsistent with the labeled dosage directions.

Key recommendations in the guidance include:

- Dosage delivery devices should be included for all orally ingested OTC liquid drug products
- Devices should be marked with calibrated units of liquid measurement (e.g., teaspoon, tablespoon, or milliliter) that are the same as the units of liquid measure specified in the directions for the product and there should not be any unnecessary markings
- Manufacturers should ensure that dosage delivery devices are used only with the products they are packaged with
- Liquid measure markings on dosage delivery devices should be clearly visible and not obscured when the liquid product is added to the device.

According to the FDA, parents and caregivers should follow 10 tips when giving medicine to an infant or child:

- Always read and follow the Drug Facts label on your OTC medicine.
- Know the 'active ingredient' in your child's medicine.
- Give the right medicine, in the right amount, to your child.
- Talk to your doctor, pharmacist, or nurse to find out what mixes well and what doesn't.
- Use the dosing tool that comes with the medicine, such as a dropper or a dosing cup.
- Know the difference between a tablespoon and a teaspoon.
- Know your child's weight.
- Prevent a poison emergency by always using a child-resistant cap.
- Store all medicines in a safe place.
- Check the medicine three times.

The FDA recommends that anyone with questions about dosage delivery devices or how to measure liquid OTC medicines contact a physician, pharmacist, or other health care professional.

Health care professionals and patients are encouraged to report adverse events, side effects, or product quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report online: www.fda.gov/MedWatch/report.htm

[Download form](#)

(<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 800-FDA-0178

For more information:

Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products

[Kids Aren't Just Small Adults](#)

(<http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM133415.pdf>)

[FDA's Safe Use Initiative: Collaborating to Reduce Preventable Harm from Medications](#)

(<http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm>)

[Consumer Update](#) (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm253338.htm>)

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