FDA Issues Final Guidance for Liquid OTC Drug Products With Dispensing Devices

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SILVER SPRING, Md., May 4, 2011/PRNewswire-USNewswire/ --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.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO [1])

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. '/>"/>

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