Infants' TYLENOL Oral Suspension, 1 oz. Grape: Recall - Dosing System Complaints

AUDIENCE : Consumer, Pharmacy

ISSUE : McNeil Consumer Healthcare notified the public of a recall of seven lots (approximately 574,000 bottles) of Infants' TYLENOL Oral Suspension, 1 oz. Grape. There were complaints from consumers who reported difficulty using the Infants' TYLENOL SimpleMeasure dosing system. SimpleMeasure includes a dosing syringe, which a parent or caregiver inserts into a protective cover, or "flow restrictor," at the top of the bottle to measure the proper dose. In some cases, the flow restrictor was pushed into the bottle when inserting the syringe.

BACKGROUND : Infants' TYLENOL is an over-the-counter (OTC) product indicated as a pain reliever/fever reducer. The product was distributed nationwide in the United States.

RECOMMENDATION : If the flow restrictor is pushed into the bottle, the parent or caregiver should not use the product. See the Press Release for lot number and UPC codes of affected product. Consumers can visit www.tylenol.com [1] for additional information.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [2]
- Download form [3] 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 1-800-FDA-0178

[02/17/2012 - Press Release [4] - McNeil Consumer Healthcare]

[02/17/2012 - Product Photo [5] - FDA]

SOURCE [6]

Source URL (retrieved on *05/22/2013 - 11:29am*):
http://www.mdtmag.com/news/2012/02/infants-tylenol-oral-suspension-1-oz-grape-

recall-dosing-system-complaints

Links:
[1] http://www.tylenol.com
[2] http://www.fda.gov/MedWatch/report.htm
[3] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[4] http://www.fda.gov/Safety/Recalls/ucm292537.htm
[5] http://www.fda.gov/Safety/Recalls/ucm292551.htm
[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm292566.htm