Pfizer, Inc. Issues A Voluntary Nationwide Recall Of One Lot Of Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle

Monday, August 27, 2018 - 04:08pm

New York, N.Y., August 27 – Pfizer Consumer Healthcare, a division of Pfizer Inc., is voluntarily recalling one lot of **Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle** because of customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described in milliliters (mL).

Pfizer concluded that the use of the product with an unmatched dosage cup marked in teaspoons rather than milliliters has a chance of being associated with potential overdose. The most common symptoms associated with ibuprofen overdose include nausea, vomiting, headache, drowsiness, blurred vision and dizziness.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches. Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle, NDC 0573-0207-30, lot R51129 was distributed nationwide to wholesalers, distributors and retailers in the United States from May 2018 through June 2018.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle Lot and Packaging Information

NDC Lot Number Expiration Date SKU UPC Configuration/Count 0573-0207-30 R51129 11/20 F00573020730 3-0573-0207-30-0 4 FL OZ (120 ml) bottle 36 bottles/case
Pfizer, Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Pfizer, Inc. has notified wholesalers, distributors and retailers to arrange for return of any recalled product. Wholesalers, distributors and retailers with an existing inventory of the lot being recalled, should stop use and distribution and quarantine the product immediately. Wholesalers, distributors and retailers that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For instructions on returning product or additional assistance, call Stericycle at 1-800-805- 3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

If consumers have questions regarding this recall or to report an adverse event, please contact the Pfizer Consumer Healthcare Information Line at 1-800-88-Advil (1-800-882-3845). Their hours of operation are Mon-Fri, 9am-5pm EST.

Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.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 1-800-FDA-0178.
This recall is being executed with the knowledge of the U.S. Food and Drug Administration. The Bottle label is shown below:

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Pfizer Inc. Media Contact: Jessica Smith, (212) 733-6213 Jessica.m.smith@pfizer.com