COMPANY ANNOUNCEMENT

GSK Consumer Healthcare Issues Voluntary Nationwide Recall of Children's Robitussin® Honey Cough and Chest Congestion DM and Children's Dimetapp® Cold and Cough Due to Dosing Cups Missing Some Graduation Markings

Summary

Company Announcement Date:

June 18, 2020

FDA Publish Date:

June 18, 2020

Product Type:

Drugs
Over-the-Counter Drugs

Reason for Announcement:

Incorrect dosing cups

Company Name:

GSK Consumer Healthcare

Brand Name:

Robitussin

Product Description:

Cough and cold products

Company Announcement

GSK Consumer Healthcare is voluntarily recalling to the retail level two lots (listed below) of Children's Robitussin® Honey Cough and Chest Congestion DM and one lot of Children's Dimetapp® Cold and Cough, due to the inclusion of incorrect dosing cups. During the review of

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the packaging documents for these products, GSK discovered that the dosing cups for the Children's Robitussin® Honey product are missing the 5 mL and 10 mL graduations, while the dosing cups for the Children's Dimetapp® product are missing the 10 mL graduation. The dosing cups packaged with both products only have the 20 mL graduation.

There is a potential risk of accidental overdose if caregivers dispensing the syrup do not notice the discrepancies between the graduations printed on the dosing cups and the indicated amounts to be administered (as directed in the instructions for use). Children's Robitussin Honey Cough & Chest Congestion DM contains 10 mg dextromethorphan HBr USP and guaifenesin USP 100 mg per 10 mL, and is labeled for children 4 and older, as well as adults. Children's Dimetapp Cold & Cough contains 2 mg brompheniramine maleate USP, 10 mg dextromethorphan HBr USP, and 5 mg phenylephrine HCl USP per 10 mL, and is labeled for children 6 and older, as well as adults. Symptoms of overdose of either product may include any of the following: impaired coordination; brain stimulation causing increase in energy, elevation in blood pressure, heart rate, and respiration; a lack of energy and enthusiasm; severe dizziness or drowsiness; slow heart rate; fainting; psychotic behaviour; restlessness; seizure; decreased respiration; nausea; vomiting; constipation; diarrhea; abdominal pain; visual and hearing hallucinations; urinary retention. As of the date of the recall announcement, GSK Consumer Healthcare has not received any adverse events related to these products or consumer complaints regarding the incorrect dosing cups supplied with the product.

The recall is limited to the three lots listed below:

Children's Robitussin® Honey Cough and Chest Congestion DM (4oz)	**Children's Dimetapp® Cold and Cough (8oz)**
NDC 0031-8760-12	NDC 0031-2234-19
Lots: 02177 (Exp. Jan. 2022) 02178 (Exp. Jan. 2022)	**Lot: CL8292 (Exp. Sep. 2021)**

These lots were distributed nationwide between February 5, 2020 and June 3, 2020 within the United States. GSK Consumer Healthcare has notified wholesalers, distributors and retailers to arrange for return of any recalled product. Wholesalers, distributors and retailers with an existing inventory of the lots being recalled should stop distribution and quarantine these lots 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.

Consumers with questions regarding this recall or to report an adverse experience please call 1-800-762-4675, Monday – Friday, 8:00am – 6:00pm EST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

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Adverse reactions or quality problems experienced with the use of this product may 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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 conducted with the knowledge of the U.S. Food and Drug Administration.

In December 2018, GlaxoSmithKline plc reached an agreement with Pfizer, Inc. to combine their consumer health businesses into a new Joint Venture. August 01, 2019 was the first day of the new GSK Consumer Healthcare Joint Venture. Thus, when identifying impacted product, please be aware the Pfizer company name will still be present on the label.

Company Contact Information

Consumers:

GSK Contact Center

1-800-762-4675

Product Photos

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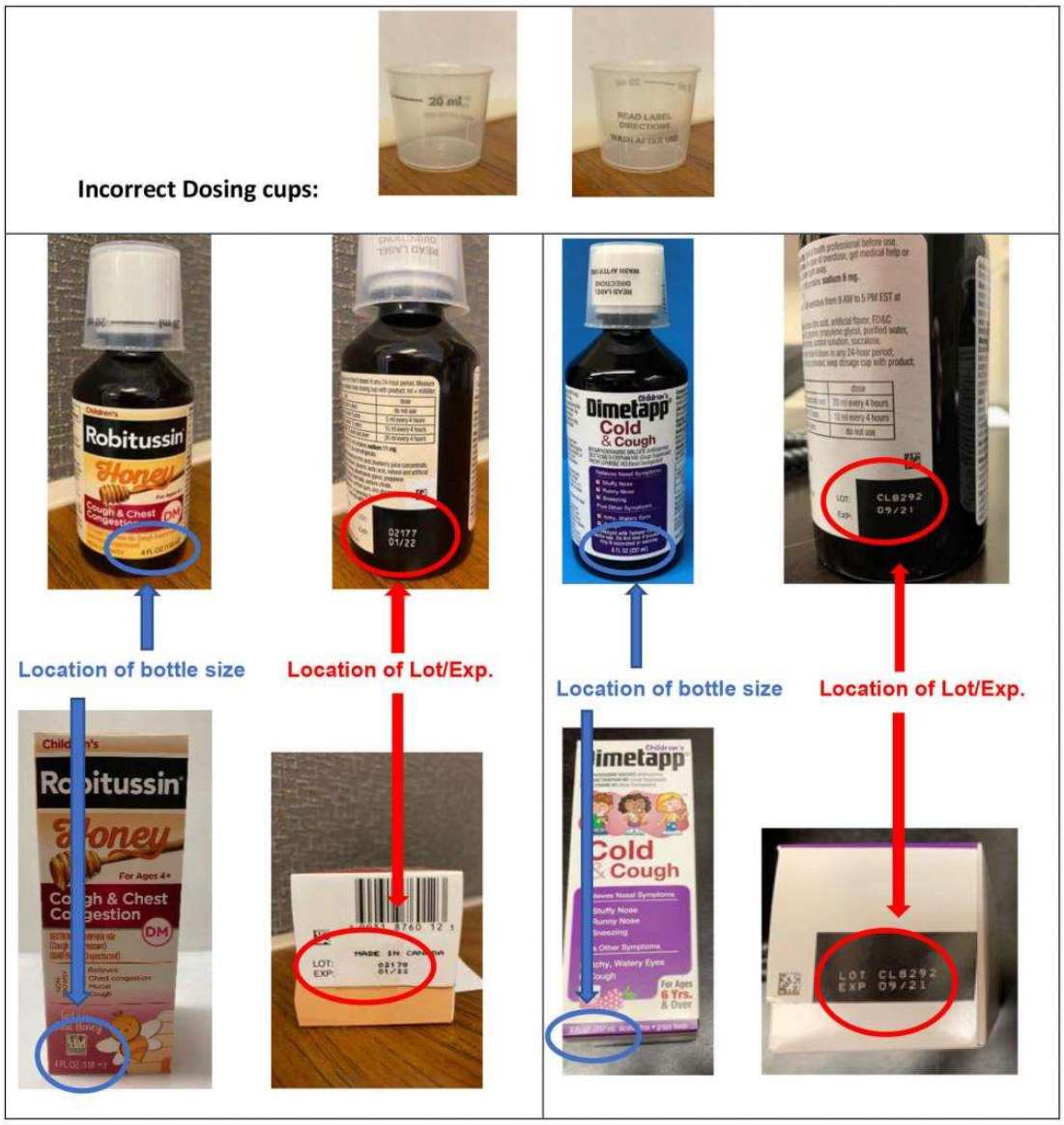

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