J & J Consumer Health Segment Recalls Infant Tylenol

LINDA A. JOHNSON, AP Business Writer

TRENTON, N.J. (AP) — Recall-plagued Johnson & Johnson is pulling all infant Tylenol off the U.S. market because some parents have had problems with redesigned bottles, introduced three months ago, that the company touted as a big safety improvement to make measuring doses easier.

Instead, 17 parents or caregivers have complained that a protective cover on the top of the bottles didn't work correctly. It's meant to limit how much of the liquid pain and fever reducer can be drawn into a plastic syringe. But when those consumers inserted the plastic syringe, it pushed the protective cover, or flow restrictor, into the bottle.

J&J's McNeil Consumer Healthcare unit, which has had about 25 product recalls since September 2009, said Friday that it is recalling all 574,000 bottles of grape-flavored, liquid Infants' Tylenol from stores nationwide.

"Today's news about the Infants' Tylenol recall is clearly disappointing after all the progress that McNeil has been making to ensure its products meet the highest level of quality and consumer satisfaction," CEO William Weldon said in a statement.

Last spring, Weldon told shareholders at J&J's annual meeting that the company was simplifying the packaging to "help a mom, dad or caregiver ensure the correct dosing." Weldon told The Associated Press then that he thought the new design would become the industry standard.

Infants' Tylenol is one of the first nonprescription medicines reintroduced after all the recalls and an ongoing factory shutdown have kept most McNeil medicines off the market, some for nearly 2 years. That's cost the company well over $1 billion in lost revenue, plus many millions to rebuild one factory and upgrade others.

McNeil spokeswoman Bonnie Jacobs said it was too soon to say when the product will return to the market.

"We are looking at various alternatives for the redesign of the dosing system and will set a timeline ... once we've reviewed all the options," she said.

The company said customers can continue to use the infant Tylenol if the bottle's flow restrictor remains intact. If not, they can request a refund by contacting McNeil at 1-888-222-6036 or www.tylenol.com.

While babies are particularly vulnerable to excessive doses of medicine, J&J said there have been no reports of anyone being harmed.

The new infant Tylenol bottle comes with a plastic syringe that's to be inserted into the flow restrictor at the top to help measure the right dose. The syringe has an opening in the tip but no needle. Consumers are to insert the tip of the syringe into the flow restrictor, turn the bottle upside down and then draw out the right dose using the milliliter markings on the syringe. That's then squirted into the baby's mouth.

McNeil changed the design to make it easier to get the dose right and to limit spillage if the bottle is knocked over, McNeil spokeswoman Barbara Montresor said. The prior version had an open-topped bottle and a dropper with a flexible bulb at the top, similar to a turkey baster.

McNeil is part of the consumer health business segment at J&J, which is based in New Brunswick, N.J. The company's prescription drug and medical device divisions each have issued at least two recalls in the last couple years.

Reasons for the recalls have included nauseating package odors, small glass or metal particles in liquid medicines and wrong levels of active ingredients.

Video showing how dose restrictor works: www.youtube.com/tylenol *[1]*

AP Business Writer Tom Murphy in Indianapolis contributed to this story.

Linda A. Johnson can be followed at http://twitter.com/LindaJ_onPharma *[2]*

Links:
[1] http://www.youtube.com/tylenol
[2] http://twitter.com/LindaJ_onPharma