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**TEMPORARY SUSPENSION  
OF THE USE OF ROTARIX®:  
INFORMATION FOR PARENTS**

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The Food and Drug Administration (FDA) has asked doctors to temporarily stop using one of the two rotavirus vaccines available in the United States. The vaccine is called ROTARIX® (Rotavirus Vaccine, Live, Oral) and is made by GlaxoSmithKline (GSK). The FDA recommended this action as a precaution after GSK notified them about the presence in the vaccine of material from a virus called PCV-1. PCV-1 is a virus not known to cause illness in humans. It is found in everyday meat products and is frequently eaten and does not result in disease or illness.

The FDA stated that ROTARIX has been extensively studied, before and after approval, and found to have an excellent safety record. The ROTARIX vaccine that your child received has passed all routine safety tests before being sent to your doctor's office.

FDA, along with GSK, has found that there is no evidence for a safety concern with the vaccine. Nevertheless, as a precaution, the FDA has recommended that doctors temporarily suspend use of ROTARIX while GSK continues its investigation relating to the presence of the PCV-1 material.

Up to today, more than 69 million doses of ROTARIX have been distributed throughout the world.

**WHAT IS ROTAVIRUS?**

Rotavirus is a virus that causes severe diarrhea, often accompanied by vomiting and fever, mostly in babies and young children.

**ABOUT ROTAVIRUS VACCINES**

There are 2 brands of rotavirus vaccine, both of which are given orally (by mouth), not as a shot. A baby should get either 2 or 3 doses, depending on which brand is used. The doses are recommended at 2 months and 4 months of age, and for one brand, also at 6 months of age.

**FOR PARENTS OF CHILDREN WHO WERE GIVEN ROTARIX**

There is no evidence that PCV-1 can infect or cause illness in humans. ROTARIX has an excellent safety profile based on extensive clinical trials and experience with use after approval in the US and elsewhere.

If your child received 2 doses of ROTARIX, you do not need to have him or her vaccinated again. The strength and effectiveness of ROTARIX is fine. If your child received the first dose only, according to the recommendation of the Centers for Disease Control and Prevention (CDC), your child should receive an additional 2 doses of the other rotavirus vaccine.

If you have any questions about ROTARIX or rotavirus vaccination in general, ask your doctor or nurse.