



REPUBLIC OF THE PHILIPPINES  
**DEPARTMENT OF HEALTH**  
**BUREAU OF FOOD AND DRUGS**

Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City  
Website: [www.bfad.gov.ph](http://www.bfad.gov.ph)  
tel no.: (02) 807-0751



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## **PUBLIC HEALTH ADVISORY**

14 April 2010

**DOH-FDA Advisory**  
**No. 2010- 005**

**SUBJECT: ROTARIX VACCINE**

In the interest of public health and safety and in the wake of recent developments and reports from international regulatory bodies, the Food and Drug Administration (FDA) issues this advisory regarding the use of ROTARIX, a vaccine which is administered to young children as a preventive measure against rotaviruses infection. It has been discovered that a porcine circovirus-1 (PCV-1) is present in the cell bank of the Rotarix vaccine. The manufacturer of the above vaccine initiated extensive experiments and confirmed the said finding.

Other regulatory agencies issued statements that the virus does not pose any public health risk as it does not cause any diseases in humans. Notably, the World Health Organization Global Advisory Committee on Vaccine Safety (WHO-GACVS) considers that the benefits of vaccination far outweigh any currently known risk associated with the use of ROTARIX given the extensive clinical data supporting the safety of the said vaccine and the benefits of rotavirus vaccination for children.

Relative thereto, the FDA advises the public of its decision that there is no need to withdraw the vaccine from the Philippine market. The FDA will continue to coordinate closely with the manufacturer and evaluate data submitted by the company and other information available from other sources. In the meantime, doctors may continue giving the vaccine to their patients based on their discretion and professional judgment.

*NAZARITA T. TACANDONG*  
NAZARITA T. TACANDONG, RPh, MPA  
Acting Director IV