

REPUBLIC OF THE PHILIPPINES

DEPARTMENT OF HEALTH BUREAU OF FOOD AND DRUGS

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04 May 2010

DOH-FDA ADVISORY No. 2010-006

SUBJECT:

Reported Recall of Certain Infant and Children and

Over-the Counter Products Manufactured in the United States

There has been report of a voluntary recall in the United States initiated by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc, and a subsidiary of Johnson & Johnson in consultation with the U.S. Food and Drug Administration of certain pharmaceutical products, specifically, Tylenol, Motrin, Zyrtec and Benadryl due to manufacturing deficiencies which may affect the quality or potency of the products. Reports have it that the affected products involve liquid preparations intended for infant and children. These products were manufactured in the United States and distributed in the United States, Canada, Dominican Republic, Dubai (UAE), Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad and Tobago, and Kuwait.

In the interest of protecting public health and safety, the public is hereby advised that records of this Office show that none of those affected batches of the products are being brought into the country. The registered counterpart pharmaceutical products available in the country are manufactured either locally or outside of the United States. Upon the other hand, the respective licensed importer-distributors and marketing authorization holders of the counterpart products registered with this Office confirmed that they have not imported or marketed in the country any of the recalled products.

Anyone who may have individually brought into the country the affected products for personal use are advise to discontinue using the same.

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Acting Director IV