Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

06 July 2012

DOH-FDA ADVISORY
No. 2012-006

SUBJECT: Reported Recall of Dextromethorphan HBr + Guaifenesin (Robitussin DM) Syrup

Pfizer Consumer Healthcare has informed this Office of its voluntary recall of its Robitussin DM product which contains Dextromethorphan HBr 15 mg and Guaifenesin 100 mg per 5 mL, due to error in labeling. Reports have it that the affected products have discrepancies on both the primary label and carton regarding the dosage instruction as follows:

Age Group	**Dosage**	**Administration**
2 to under 6 years	2.5 mL (1 teaspoonful) ***should have been ½ teaspoonful***	Every 6 hours
6 to under 12 years	5 mL (1 teaspoonful)	Every 6 hours
12 years to Adult	10 mL (2 teaspoonfuls)	Every 6 hours
Do not exceed recommended dosage. For children 2 to under 6 years of age consult a healthcare professional before use.		

Continuous distribution of the said product present health risk to the consuming sector of the public. Thus, anyone who may have bought the affected products are advise to discontinue using the same and immediately coordinate with the above establishment.

NICOLAS B. LUTERO, III, Esq., CESO III
Assistant Secretary of Health
Officer-In-Charge – Food and Drug Administration