Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

20 March 2014

FDA Advisory No. 2014-026

SUBJECT: VOLUNTARY PRODUCT RECALL OF BATCH SPECIFIC TRIFLUSAL 300mg CAPSULE (GRENDIS)

This is to inform the public that Abbott Laboratories (Philippines) has initiated a voluntary recall of Triflusal 300mg capsule (Grendis) up to the retail level. The details of the product are as follows:

REGISTRATION NUMBER	**DR-XY30166**
BATCH NUMBER	**H003**
DATE OF MANUFACTURE	**MARCH 2013**
EXPIRY DATE	**MARCH 2016**
MANUFACTURING NAME AND ADDRESS	**J. URIACH & CIA, S.A. AV. CAMI REIAL 51-57, 08184 PALAU-SOLITA I PLEGAMANS, BARCELONA, SPAIN**

Abbott received a complaint from the Malaysian market that another batch of the product (H005) which has been distributed to Malaysia had a "Bad Smell". The result of the investigation of the manufacturing site concluded that the bad smell was due to an increase of one known impurity named HTB, 4-trifluoromethylsalicylic acid (also known as 2-hydroxy-4-(trifluoromethyl)benzoic acid. The increase in the impurity is related to a damage of the refrigeration system of the equipment used in the manufacturing process of the Active Pharmaceutical Ingredient (API).

The batch number H003 distributed in the Philippines was manufactured using a different lot number of API (Triflusal) that is from that of the complaint batch (H005). However, the API manufacturing site confirmed that batch H003 was impacted by the same event (damage of refrigerator system).

All pharmacies should locate and remove the affected product batch from their facility. Consumers are advised not to use the affected batch of the product, and return it to where it was purchased.

Triflusal is an antiplatelet drug indicated for secondary prevention after a first coronary or cerebrovascular ischemic event of myocardial infarction, stable and unstable angina, non-hemorrhagic stroke or transient ischemic attack, and reduction of vein graft occlusion after coronary bypass surgery.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any adverse reaction caused by the aforementioned product should be reported immediately to FDA at report@fda.gov.ph.

KENNETH HARTIGAN-GO, MD
Acting Director General