



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



24 November 2014

FDA Advisory  
No. **2014-086**

**SUBJECT: TERMINATION OF BATCH SPECIFIC PRODUCT RECALL**  
**ORDER ISSUED ON TRIFLUSAL (GRENDIS) 300 mg CAPSULE**

This is to inform the public that the recall order issued on batch H003 of Triflusal (Grendis) 300 mg Capsule with registration number DR-XY30166 is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by J. Uriach & CIA, S.A. in Barcelona, Spain.

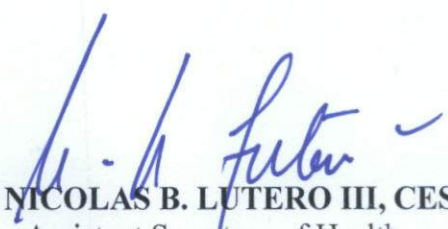
As per FDA Advisory No. 2014-026 dated 20 March 2014, Abbott Laboratories (Philippines) voluntarily recalled batch no. H003 of Triflusal (Grendis) 300 mg Capsule because of "bad smell" of the product which resulted from increased amounts of a known impurity, namely HTB,4-trifluormethylsalicylic acid, due to damage in the refrigeration system of the equipment used in the manufacturing process of the Active Pharmaceutical Ingredient (API).

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), Abbott Laboratories (Philippines), to recall and properly destroy the impacted product batch in accordance with Bureau Circular No. 8, s. 2001, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be any findings of any violation of existing laws, rules and regulations.

All field Food and Drug Regulation Officers are ordered to monitor and seize the cited product batch if found available in the market.

Consumers may contact the FDA at telephone number +632 857-1900 or via e-mail at [info@fda.gov.ph](mailto:info@fda.gov.ph) for any questions or additional information regarding this recalled product.

  
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