DELISTING OF ROFECOXIB FROM BUREAU OF FOOD AND DRUGS REGISTRY OF DRUG PRODUCTS

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The Bureau of Food and Drugs, after careful evaluation of the recent voluntary withdrawal of ROFECOXIB from the Philippine market by its local company Merck Sharp & Dohme Philippines, has determined that all Rofecoxib formulations will no longer be registered due to increased risk of serious cardiovascular events, including heart attacks and strokes. Furthermore, pending applications for registration will no longer be processed and future submissions will not be accepted.

All pharmacists/owners of drugstores and drug outlets are hereby reminded that importation, distribution or sale of unregistered products is subject to sanctions and penalties stipulated in R.A. 3720, as amended, otherwise known as the "Foods, Drugs, and Devices and Cosmetics Act" and R.A. 8203, the "Special Law on Counterfeit".

In the interest of public health and safety, the Agency warns all drugstore owners, pharmacists and the consumers against dispensing/selling, and using the above-mentioned unregistered product. Doctors and other health practitioners are also warned against using this product to their patient. For strict and immediate compliance.

Adopted: 26 Nov. 2004

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Director

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