

DELISTING ORAL PROTEOLYTIC ENZYME-CONTAINING DRUG PRODUCTS IN THE REGISTRY OF DRUGS WITH THE BUREAU OF FOOD AND DRUGS (BFAD)

BFAD ADMINISTRATIVE ORDER NO. 16, May 13, 1999

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On the basis of the following findings and recommendations of the National Drug Committee of the Department of Health:

- Oral Proteolytic Enzyme — Containing Drug Products which are labeled for use in controlling edema and inflammation associated with surgical, obstetrical or dental procedures or accidental trauma to any part of the body of infectious or allergic manifestations have not been shown to be effective for such uses;
- There are inadequate data to prove their safety (e.g. animal studies based on acute, chronic and special studies in teratogenicity and carcinogenicity) contrary to claims;
- The indications for which some of the Oral Proteolytic-Enzyme Containing Drug Products were initially registered and subsequently re-registered differed.

This Office determines that there is no basis to retain Oral Proteolytic Enzyme — Containing Drug Products in the registry of drug products in the Philippines.

Wherefore, Oral Proteolytic Enzyme — Containing Drug Products in the registry of drug products in the Philippines.

Wherefore, Oral Proteolytic Enzyme-Containing Drug Products are delisted from the registry of drug products and shall, henceforth, no longer be registered in BFAD.

The BFAD is directed to implement an orderly phase-out of all the existing Oral Proteolytic-Enzyme Containing Drug Products in the market.

This Administrative Order shall take effect immediately.

Adopted: 13 May 1999

(SGD.) ALBERTO G. ROMUALDEZ, JR. M.D.
Secretary of Health

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