

November 11, 1992

ADMINISTRATIVE ORDER No. 5, s. 1992

SUBJECT: Banning of Loperamide Hydrochloride Liquid Preparation for Children

The National Drug Committee and the Bureau of Food and Drugs recommended the banning of loperamide hydrochloride liquid preparations for children because –

- (1) "children are more sensitive to its (loperamide) adverse CNS (central nervous system) effects."
- (2) "its (loperamide) safety and efficacy in children are not yet established"

This recommendation is supported by the December 21-28, 1990 issue of the Weekly Epidemiological Record from WHO (p. 398).

FINDING the foregoing recommendation in the interest of safety and consumer's protection, loperamide hydrochloride liquid preparation for children is hereby banned.

This preparation shall no longer be registered for distribution in the market.

The BFAD shall ensure that no loperamide liquid preparation is introduced henceforth in the market.

This Order shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

(Sgd) JUAN M. FLAVIER, M.D., M.P.H. Secretary of Health

Date Approved: 11/16/92