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Republic of the Philippines
Ministry of Health
OFFICE OF THE MINISTER
Manila

7260
BUREAU OF FOOD & DRUGS
RECEIVED
BY *Schya*
ON *11-4-85*
OFFICE OF THE MINISTER
September 5, 1985

ADMINISTRATIVE ORDER
No. 129 s. 1985

SUBJECT : Banning and withdrawal of FLOSINT TABLETS
(INDOPROFEN) from the market.

While the anti-inflammatory efficacy of Indoprofen which is marketed as FLOSINT has been established through the years, recent preliminary results of long-term studies on the drug led to a further toxicological investigation.

Contrary to previously established studies, recent researches and further studies conducted in various animal species indicate that prolonged treatment induces irritative and ulcerous changes of the gastro-intestinal tract of the treated animals. Instances of the presence of tumors were also found.

O R D E R

1. In the interest of consumer protection FLOSINT TABLETS (INDOPROFEN) is no longer registrable.
2. Henceforth, the registration of the above-mentioned product is hereby recalled and cancelled.
3. All existing stocks from drugstores, hospitals, etc. should be recalled by the importer/distributor and destroyed in the presence of BFI Inspectors.

This Order takes effect immediately.

Recommended by:

(SGD.) CATALINA C. SA CUEZ
Director

Approved:

(SGD.) J. C. AZURA
Minister of Health

CERTIFIED TRUE COPY:

Gregoria V. Bautista
GREGORIA V. BAUTISTA
Chief, Records Section
Ministry of Health
Manila

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