

## REPUBLIC OF THE PHILIPPINES MINISTRY OF HEALTH BUREAU OF FOOD AND DRUGS MANILA

August 28, 1985

ADMINISTRATIVE ORDER NO./30 s. 1985

SUBJECT: Banning and withdrawal of SULOCTION (SULOCTIDIL) from the market.

While the efficacy of Sulocton containing Suloctidil as active ingredient has been established through the years, documented studies undertaken on Sulocton (Suloctidil) indicate hepatic adverse effects related to its administration. Based on tabulated reports the most prevalent clinical diagnosis is "Cytolitic Hepatitis" or jaundice. Cholestatic elements are sometimes present as well as cirrhotic background. In few cases, persistent alterations of liver function or structure were also documented.

## CRDER

- 1. In the interest of consumer protection Sulocton (Suloctidil) is no longer registrable.
- 2. Henceforth, the registration of the said 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 BFAD Inspectors.

This Order takes effect immediately.

Recommended by:

CATALINA C. SANCHYZ Director

Approved:

AZURIN Minister of Health