

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY Manila

ADMINISTRATIVE ORDER

NO. 341 s. 1978

SUBJECT: <u>Ban on the Use of Chloroform (trichloromethane).</u>

Chloroform has a long history of use in drugs and cosmetics. The current usage of chloroform in drug products is for its antitussive and carminative properties in products taken orally, for its counter-irritant property in liniments, as a preservative, as a flavoring and as a solvent during the manufacturing process. In cosmetics it is likewise used as a flavoring agent.

However, a recent study carried out by the National Cancer Institute in the United States suggests that Chloroform may be carcinogenic in rats and mice when administered over prolonged periods. Although there is no direct evidence that chloroform as used in drugs and cosmetics, has caused injury to the health of humans, the new finding raised doubts about the long term safety of this ingredient. As with any animal carcinogen, chloroform must be considered as potential human carcinogen.

In the interest of consumer protection therefore, and as a guidance to pharmaceutical manufacturers, distributors and retail outlets, the use of chloroform as an ingredient in human drugs and cosmetics is hereby prohibited effective April 30, 1978.

No recall of existing products are required. Manufacturers, distributors and retail outlets of products containing chloroform would be permitted to continue sale of these products up to June 30, 1978 in order to provide for an orderly conversion to reformulated products and phase out of present inventory.

Products containing chloroform and not in accordance with this regulation shall be deemed adulterated within the meaning of Sec. 14 (a) of the Food, Drug and Cosmetic Act (RA 3720).

Recommended by:

(Sgd) ARSENIO M. REGALAFood and Drug Administrator

Approved by:

(Sgd) CLEMENTE S. GATMAITAN, M.D., M.P.H.
Minister of Health