

October 13, 1972

ADMNISTRATIVE ORDER

No. 179 s. 1972

SUBJECT: Restricted Use of Hexachlorophene

It has been conclusively established that hexachlorophene can be absorbed through the skin of humans with toxic effect including death. It has also been established that hexachlorophene is a useful bacteriostatic skin cleanser when used according to direction.

In the interest of consumer protection, products containing hexachlorophene other than as preservative, will be considered as a drug available only in drugstores and on prescription. This reclassification will require the registration of such product as a drug and subject to all drug requirements.

ORDER

- 1. Talcum powder intended for infant use containing more than 0.75 percent Hexachlorophene shall be recalled by the manufacturer.
- 2. All other products (except talcum powder) containing more than 0.75 percent hexachlorophene shall be made available only in pharmacies or drugstores and on prescription. Such products in other retail or non-professional outlets where there is no pharmacy shall be recalled by the manufacturer. All these products shall be relabeled as prescription drug and to carry the Rx symbol.
- 3. All products containing less than 0.75 percent need not be recalled by the manufacturer. Existing stocks in stores may be utilized until the end of 1972. However, production and distribution of these products shall immediately cease.

Effective January 2, 1973, products containing more than 0.75 percent hexachlorophene will be considered misbranded (1) for over-the-counter distribution or (2) if the legend "Caution: Food, Drug and Cosmetic Law prohibits dispensing without a prescription" is not stated on the Label.

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Recommended by:

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