

USE OF HYDROQUINONE AND/OR TRETINOIN (RETINOIC ACID)

BFAD ADMINISTRATIVE ORDER NO. 13, S. 1999, April 06, 1999

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In accordance with the provisions of Republic Act No. 3720, otherwise known as Foods, Drugs, Devices and Cosmetics Act, as amended, the following regulation is hereby promulgated:

- All preparations containing less than, or equal to two percent (2.0%) Hydroquinone are to be classified as home remedies and therefore can be sold without the supervision of a pharmacist. Provided, however, that labelling as to its proper use is adhered to.
- All preparations containing more than two percent (2.0%) but less than three percent (3.0%) Hydroquinone are classified as over-the -counter drugs. All preparations containing more than 3.0% Hydroquinone are considered prescription drugs. Appropriate labelling as to its proper use, and warnings as to its possible adverse effects, must be indicated.
- All preparations containing less than or equal to twenty -five hundredths percent (0.025%) of Tretinoin (Retinoic Acid) are classified as home remedies and need not be dispensed under the supervision of a pharmacist, provided however, that labelling as to its proper use, is adhered to.
- All preparations containing more than 0.025% but less than or equal to 0.05% Tretinoin are classified as OTC drugs. Preparations containing more than 0.05% Tretinoin are considered prescription drugs. Appropriate labelling as to its proper use and warnings as to its possible adverse effects must be indicated.
- Combinations of Hydroquinone and Tretinoin provided they do not individually exceed the maximum amounts for each active component of 2% for Hydroquinone and 0.025% for Tretinoin, are also classified as home remedies, and therefore need not be dispensed under the supervision of a pharmacist. Provided however, that labelling as to its proper use, is adhered to.

All other Administrative issuance or parts thereof, inconsistent with the provisions of this Order are hereby amended, repealed and modified accordingly.

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

Adopted: 6 April 1999

(SGD.) ALBERTO G. ROMUALDEZ, JR., M.D.
Secretary of Health

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