

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

March 26, 2001

ADMINISTRATIVE ORDER No. 1-A, s. 2001

SUBJECT: USE OF HYDROQUINONE AND/OR TRETNOIN (RETINOIC ACID)

In accordance with the provisions of Republic Act 3720, otherwise known as Food, Drugs, Devices and Cosmetic Act, as amended, the following amendments to A.O. 13 s. 1999 are promulgated:

- 1. All preparations containing hydroquinone as the only active ingredient in concentrations not exceeding 2% are classified as cosmetics;
- 2. All preparations containing hydroquinone as the only active ingredients in concentrations exceeding 2% but not more than 4% are considered prescription drugs and as such are to be dispensed only in registered drug outlets by a licensed pharmacist
- 3. All preparations containing more than 4% hydroquinone are not allowed and are not registrable;
- 4. All preparations containing hydroquinone up to 4% and in combination with tretinoin or similar compounds are claSSIfied as prescription drugs as in (2);
- 5. All preparations containing tretinoin as the only active ingredient are classified as:
- i) Household remedy, if the concentration of tretinoin does not exceed
- 0.05% for creams
- 0.025% for gels and lotions
- ii) Prescription drug if the concentration of tretinoin exceeds
- 0.05% for creams
- -0.025% for gels and lotions
- 6. All preparations containing tretinoin in any amount but in combination with another active compound are classified as prescription drugs.

Appropriate labeling as to its preper use and adequate warnings as to its possible side effects must be indicated for all products with hydroquinone, tretinoin or any combination thereof.

All other administrative issuances 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hereby amended, repealed and modified accordingly.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.

MANUEL M. DAYRIT, MD, MSc.

Secretary of Health