Republic of the Philippines
Ministry of Health
OFFICE OF THE MINISTER
Manila

June 30,1982

ADMINISTRATIVE ORDER
No. 33 s. 1982

SUBJECT: **Reclassifying Ephedrine And Ephedrine-containing Cough Syrup From "Over- The-Counter" Drugs To Prescription Drugs.**

Ephedrine preparations (ephedrine, ephedrine hydrochloride, ephedrine sulfate) have been found to be safe and effective for OTC use as bronchodilators in adults in oral dosage of not more than 25 mg per unit dose, not more often than 4 hours.

Ephedrine produces in addition to nasal decongestion and bronchodilation, some Stimulation of the central nervous system, wakefulness, elevated mood, moderately raised blood pressure, quickened pulse rate together with raised cardiac output, it is contraindicated in the presence of coronary thrombosis, hypertension, hyperthyroidism, and close-angle glaucoma. It should be given with caution to patients with organic heart disease, cardiac decomposition or angina of effort.

However, one significant finding is that ephedrine- containing preparations should not be given to children under 12 years of age except under the advice and supervision of a physician. This particular age group constitutes a substantial segment of the population and deserves protection more than any other group. Obviously, protection would be inadequate if ephedrine-containing preparations which are the most commonly available to this group were to remain classified as over-the -counter drugs. These should therefore be classified as prescription drugs with the Rx symbol clearly indicated on the labels.

Accordingly, Ephedrine, alone or in combination, when used in liquid preparations, will be considered misbranded.

1. for "over-the-counter" distribution; or
2. if the "Rx" symbol and the warning "Caution: Food, Drug and Cosmetics Law prohibits dispensing without prescription"- are not stated on the label.

O R D E R S

1. (a) Pharmaceutical preparations in liquid form containing Ephedrine alone or in combination are no longer "over-the-counter" preparations.

   (b) Henceforth, the registration of the above-mentioned pharmaceutical preparations as "over-the-counter" drug products is hereby recalled and cancelled.

2. For the orderly phasing out of stocks which have been distributed to retail outlets prior to the issuance of this Order, all stocks should have been recalled and withdrawn by the manufacturer or distributor for proper correction of the label as required in this Order by September 30, 1982.

This Order supersedes all orders, rules and regulations or parts thereof inconsistent herewith and shall take effect on October 1, 1982.

**(Sgd) J.C. AZURIN**
**Secretary of Health**