**Republika ng Pilipinas**
**Ministri ng Kalusugan**
**PANGASIWAAN NG PAGKAIN AT GAMOT**
**(Food and Drug Administration)**
**Lungsod ng Maynila**

June 11, 1979

**ADMINISTRATIVE ORDER**
**NO. 34 s. 1979**

**SUBJECT: THE NEED AND ROLE OF A MEDICAL DIRECTOR IN THE PHARMACEUTICAL INDUSTRY**

To facilitate the objective evaluation of New Drug, to provide adequate information to the consuming public, and to ensure safety and efficacy of drug to protect the health of the people, this Regulation is hereby promulgated.

1. Pharmaceutical laboratories and drug departments handling and dealing in new drugs must have a Medical Director on a full time, part time or consultancy basis, who is a registered physician with knowledge and training in basic or clinical pharmacology.

2. The Medical Director must be registered with the Food and Drug Administration by the management of the pharmaceutical laboratory and drug department.

3. All communication with the Food and Drug Administration regarding New Drugs and Investigational New Drugs including the follow-up of application for registration of New Drugs, Investigational New Drugs and matters arising from clinical investigation must be coursed through the Medical Director with the assistance of the registered pharmacist of the establishment.

4. All packages, inserts, labeling, brochures and other labeling/promotion materials must be approved by the Medical Director with the assistance of the registered pharmacist of the establishment prior to submission to the Food and Drug Administration.

5. This Regulation shall take effect immediately upon approval.

**Recommending Approval:**

**(Sgd) ARSENIO M. REGALA, Ph.D.**
Administrator

**APPROVED BY:**

**(Sgd) CLEMENTE S. GATMAITAN, M.D., MPH**
**Minister of Health**