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

January 30, 1986

ADMINISTRATIVE ORDER
No. 7 s. 1986

SUBJECT : **Amending A.O. No. 133 s. 1985 Re: Guidelines on the evaluation and registration of Fixed Dose Combination**

FIXED DOSE COMBINATION drugs are pharmaceutical preparations consisting of two or more ingredients possessing similar or different pharmacologic actions.

he advantages offered by fixed dose combinations in simplifying prescribing, encouraging patient compliance, reducing cost and in general, simplifying therapy are well recognized and accepted.

In order to register fixed dose combination drugs, the following data are required:

1. A detailed statement stipulating the rationale for using the combination based on the above mentioned advantages.

2. Information on the pharmaceutical, pharmacological, therapeutic and adverse properties.

3. Toxicological studies of the combination.

4. Pharmacodynamics.

5. Bioequivalence or Bioavailability Data, where applicable, to be done on Filipino patients.

6. Clinical documents/data to support efficacy and safety.

In order to be acceptable for registration, a combination should conform with the following principles:

1. There should be pharmaceutical (chemical and/or physical) compatibility of the active ingredients in the preparation to ensure stability.
2. There should be no conflict of dosage regimen of its active ingredients.
3. Separate adjustment of dosage to achieve optimal effects in individual patients should not be necessary.
4. the combination should provide the following advantages:

    a) an additive, synergistic and/or complementary action;
    b) reduction of adverse drug reactions; and
    c) dosage convenience for better patient compliance.

This Administrative Order shall take effect immediately and supersedes A.O. No. 133 s. 1985.

(Sgd) ALFREDO R.A.BENGZON
Secretary