Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

September 18, 1989

ADMINISTRATIVE ORDER
No. 79 s. 1989

SUBJECT : Transitional Remedial Labeling In Compliance with R. A. 6675

In response to various inquiries by drug manufacturers and outlets regarding the implementation of A.O. 55, s. 1983, the following clarification are hereby issued:

1. The Bureau of Food and Drugs and the Department of Health shall implement the visions and deadlines of A. O. 55, s. 1988 except when legally prohibited from doing so. All parties engaged in manufacturing, distributing or selling drug products using labels not in compliance With A. O 55 are advised that they do so at their own risk when the deadline of the said A.O. shall take effect as stated.

2. Drug manufacturers carrying substantial inventories of drug products whose labels do not comply with the requirements of A. O. 55 may be granted by BFAD remedial labeling relief provided that they comply with the following requirements:

2.1 The drug manufacturer has a specific plan for implementing any of the remedial labeling options described below in the transition only. The plan shall indicate the drug products for which it would adopt relabeling, estimated quantity to be relabeled and the kind of relabeling option to be adopted.

3. Upon compliance with the conditions described in Section 2 above and upon approval by BFAD any of the following remedial labeling options may be availed of by drug manufacturers seeking to comply with the generics labeling requirements of R.A. 6675 for a specific lot of drug products already produced under old labeling rules. The essence of these options is that the identification of the generic name of the drug product shall be made as far as feasible under the circumstances.

3.1 For drug products in bottles, including vials containing more than 20 ml.

3.1.1 A new package insert approved by BFAD as complying with A. O. 55 must be provided.

3.1.2 The immediate container must be identified by a remedial stick on label added to the old label. The remedial label may be any of the following (a) the new label approved by BFAD under A. O. 55; (b) a label containing only the generic name derived from the label approved by BFAD under

A.O. 55.

3.1.3 The secondary container should use a new label approved by BFAD under A. O. 55 or alternatively a remedial stick on label on the principal display panel containing the generic name as approved by BFAD complying with A. O. 55

3.2 For drug products in blister packs or aluminum foil packs; vials containing not more than 20 ml. and all ampules.

3.2.1 A new package insert approved by BFAD as complying with A. O. 55 must be provided.

3.2.2 A clarificatory leaflet containing the labeling information required by A.O. 55 must be provided. The leaflet must be approximately the same Size as the basic blister pack or aluminum foil pack. There should be about one leaflet for every four tablets or capsules. This leaflet shall be distributed upon dispensing the product.

3.2.3 The secondary container should use a new label approved by BFAD under A. O. 55 or alternatively a remedial stick on label on the principal display panel containing the Generic name as approved by BFAD complying with A. O. 55.

4. These remedial labeling shall be available only for products produced prior to August 16, 1989, the starting date when all new drug production were required to use the new approved labels under A. O.
55.

5. This regulation shall take effect fifteen (15) calendar days after publication in two newspapers of general circulation or in the Official Gazette.

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Secretary of Health