Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

7 November 1991

DEPARTMENT OF HEALTH
Administrative Order No. 114-B
Series of 1991

DEPARTMENT OF AGRICULTURE
Administrative Order No. 38
Series of 1991

SUBJECT :**TRANSITIONAL REMEDIAL LABELLING IN COMPLIANCE WITH R.A. 6675**

In response to various inquiries by veterinary drug and product manufacturers and outlets regarding the implementation of joint Administrative Order DOH No. 105 s. 1991 and DA No. 11 s. 1991 the following clarification are hereby issued:

1. The Bureau of Food and Drugs and the Bureau of Animal Industry shall implement the provisions and deadlines for the joint Administrative Order DOH No. 105 s. 1991 and DA No. 11 s. 1991. All parties engaged in manufacturing, distributing or selling veterinary drug products using labels not in compliance with joint Administrative Order DOH No. 105 s. 1991 and DA 11 s.1991 are advised to observed the deadlines.

2. Veterinary drugs and product manufacturers carrying substantial inventories of veterinary drugs and products whose labels do not comply with the requirements of joint Administrative Order DOH No. 105 and DA No. 11 s. 1991 may be granted by BFAD/BAI remedial labeling options described below during the transition period only. The specific plan shall indicate the veterinary drugs and products for which it would adopt relabelling, estimated quantity to be relabeled and the kind of relabelling option to be adopted.

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

3.1 For a veterinary drugs and products in bottles, including, vials containing more than 220 ml.

3.1.1 A new package insert approved by BFAD/BAI as complying with joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s. 1991 must be provided.

3.1.2 The immediate container must be identified by a remedial stick-on label added to the old label may be any of the following (a) the new label approved by BFAD/BAI under joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s.1991; (b) a label containing only the generic name derived from the label approved by BFAD/BAI under joint Administrative Order DOH No. 105 s. 1991 and DA No. 11 s. 1991**.**

3.1.3 The secondary container should use a new label approved by BFAD/BAI under joint Administrative Order No. 105 s. 1991 and DA No. 11 s. 1991; or alternatively a remedial stick on label on the principal display panel containing the generic name as approved by BFAD/BAI complying joint Administrative Order DOH No. 105 s. 1991 and DA No. 11 s. 1991.

3.2 For veterinary drugs and 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/BAI as complying with joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s.1991 must be provided.

3.2.2 A clarificatory leaflet containing the labeling information required by joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s.1991 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 A secondary container should use a new label approved by BFAD/BAI under joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s.1991 or alternatively a remedial stick on label on the principal display panel containing the generic name as approved by BFAD/BAI complying with joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s.1991.

4. This remedial labeling shall be available only for products produced prior to October 1, 1992, the starting date when all new veterinary drug and production is required to use the new approved labels under joint Administrative Order DOH No. 105 s.1991 and DA No. 11 s.1991.

5. This regulation shall take effect fifteen (15) calendar days after publication in a newspaper of general circulation or in the official Gazette.

(Sgd.) SENEN C. BACANI
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