Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

August 1, 1990

DEPARTMENT OF AGRICULTURE

Administrative Order No. 41 Series of 1990

DEPARTMENT OF HEALTH

Administrative Order No. 111-D Series of 1990

SUBJECT: GUIDELINES ON ADVERTISEMENT AND PROMOTIONS OF VETERINARY DRUGS AND PRODUCTS

Pursuant to Section 6 (c) of R.A. 6675 known as "Generics Act of 1988" Section 3 (c) of R.A. 3720 known as "Foods, Drugs and Devices and Cosmetics Act", and Executive Order No. 119 dated January 30, 1987, the following rules and regulations on the advertisement and promotions of veterinary drugs and products are hereby promulgated.

Section 1. DEFINITION OF TERMS:

- 1.1 "Advertisement" refers to any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any veterinary drug and product.
- 1.2 "Promotion" refers to the practice of giving temporary additional value to brand, product or service to achieve specific marketing objectives. "Promotion" includes the distribution of free sample of veterinary drugs and products.
- 1.3 "Veterinary drugs and products" refer to any substance, including biological products, applied or administered to food producing, companion, aquatic, laboratory and exotic animals, whether used for therapeutic, prophylactic or diagnostic purpose or for modification of physiological functions or behavior.
- 1.4 "Veterinary Prescription or Ethical Drugs" refer any drug preparation that is to be dispensed only upon written order of a duly-licensed veterinarian for the treatment of a condition or a diagnosed disease of animals.

- 1.5 "Veterinary Non-prescription Drug" or "Veterinary Over-the-Counter Drugs" refer to drug preparations that can be dispensed even without the written order of a duly-licensed veterinarian, for the use of animals for the self-limiting animal diseases.
- 1.6 "Mass Media" refer to any publication, book, notice, handbill, poster, circular, pamphlet, letter, billboard, print media, radio, television, cinema, mobile audiovisual units or any other widespread medium of information directed to the lay public.

Section 2. GUIDELINES ON ADVERTISEMENT AND PROMOTION TO BASED ON PRIOR LAWS.

- 2. 1 No person shall advertise or promote veterinary drug and product unless such products are duly- registered with the Bureau of Food and Drugs (BFAD) and/or the Bureau of Animal Industry (BAI).
- 2.2 All therapeutic claims for veterinary drugs and product made in advertising or promotional materials must be based on adequate scientific, pharmacological, technical and clinical evidence, responsible veterinary medical opinion or long experience demonstrating their safety, efficacy and therapeutic indications approved by the BFAD and or the BAI.
- 2.3 Veterinary drugs and products classified by BFAD/BAI as Prescription of Ethical Drugs can be advertised
- or promoted in any form of mass media provided a veterinarian should be prescribing the veterinary drugs and products. This form of advertisement shall be only for a period of one (1) year or until such time that in the rural areas certified by the Philippine Veterinary Medical Association (PVMA) / Veterinary Practitioners Association of the Philippines (VPAP).
- 2.4 The Veterinary drug and product company which owns the veterinary drugs and products, and its Veterinary Medical Director/Officer shall be responsible and accountable for the content and form of their advertisement and promotion materials.

IMPLEMENT SECTION 6 (C) OF THE GENERICS ACT OF 1988 (R.A. 6675)

Section 3. GUIDELINES ON ADVERTISEMENT AND PROMOTION TO IMPLEMENT SECTION 6 (C) OF THE GENERICS ACT OF 1988 (R.A. 6675)

3.1 General Principle

Consistent with section 6 (c) of R.A. 6675, all advertising and promotional materials, whether print, visual or auditory, shall feature prominently the generic name of the veterinary drugs and products designated by BFAD/BAI. In the case of branded

products, the prominence of the generic name shall be insured in all print, visual or auditory materials but can feature the brand name.

3.2 Print and Static Visual Materials, (e.g. Posters, Billboards)

The pertinent provisions of Administrative Order No. _____ on Requirements for Labelling Materials of Veterinary Drugs and Products quoted hereunder shall apply with the exception that the word "label" shall be substituted by "advertising and other promotional material".

- 3.2.1 In all cases, the generic name shall be the prominently printed element on the advertising and other promotional material defined as the one with the highest point size among the various printed elements on the advertising and other promotional materials. It shall be enclosed exclusively by a outlined box rendered in the same color as the generic name. The background color inside the box, against which the generic name is rendered, should be the same color as the background color outside the box, against which the brand name is rendered.
- 3.2.2 In all cases, the generic name shall be printed in full, not abbreviated and in accordance with the International Non-Proprietary Name (INN). In case the salt or the specific chemical form of the drug needs to be indicated, this must be included inside the box but in small point size.
- 3.2.3 If veterinary drug and product are identified by brand names together with their generic names, the following shall be required in addition to 3.2.1 and 3.2.2.
- 3.2.3.1 The generic name and brand name shall be rendered using the same typeface, boldness, font and color, with the generic name, appearing immediately above the brand name and rendered in a point size bigger than the brand name.
- 3.2.3.2 If a brand name is presented using a special typeface exclusively designed and used for it, the generic name shall be rendered in Helvetica or Universe typeface while complying with the other pertinent provisions above.

3.3 Other Visual Materials

For other forms of visual materials, such as television, cinema or movies, etc. the general principle in 3.1 shall be applied, and consistent with the generic name designated by BFAD/BAI, shall appear prominently within the outlined box, immediately above and in larger point-size than the brand name, if any.

3.4 Auditory Materials

For auditory materials used in radio or other media, the general principle in 3.1 shall be adopted according to the convention of the medium.

Section 4. MONITORING AND ENFORCEMENT

- 4.1 The veterinary drug and product establishment under which name the veterinary drug and product is registered shall be responsible for ensuring that its advertisement and other promotional materials comply with these guidelines. It shall establish suitable mechanism for internally reviewing such materials specifically with the participation of its veterinary medical director/officer.
- 4.2 In addition, the veterinary drug and product establishment may participate in other industry-wide mechanism for self or voluntary regulation. Such participation, however, shall not in anyway diminish the fundamental responsibility and accountability of the veterinary drug and product establishment with respect to compliance with these regulations.
- 4.3 No prior clearance from BFAD/BAI is required for initial printing and broadcast or dissemination of advertisement and other promotional materials for veterinary drugs and products. However, it is incumbent upon the advertiser of the veterinary drug or product to obtain the approval of the Veterinary Technical Committee of the Board of Advertisers of the Philippines.
- 4.4 BFAD/BAI shall monitor advertisement and promotion of veterinary drugs and products as well as receive complaints regarding these. On the basis of its monitored finding or complaints, BFAD/BAI shall determine if any advertising or promotional material violates these guidelines.
- 4.5 Any advertising or promotional material found to be violative of these guidelines shall be identified and the veterinary drug and product establishment responsible shall be notified. BFAD/BAI shall issue a cease and desist order stopping the further release, printing broadcast or dissemination of the violative advertising or promotional material.
- 4.6 If the veterinary drug and product establishment wishes to contest BFAD/BAI findings, a formal hearing shall be conducted. From the finding after the hearing, BFAD/BAI shall decide along the following possibilities:
- 4.6.1 The initial finding was found untenable and the cease and desist order is then lifted.
- 4.6.2 The initial finding was found valid so the cease and desist order remains.

- 4.7 Repeated or serious violations of these guidelines may be regarded by BFAD/BAI as indicative of the subject veterinary drug and product establishment's inability to perform adequately in a manner that assures the proper use of its veterinary drugs and products. Under such condition and after due hearing,BFAD/BAI may impose the following sanctions:
- 4.7.1 Withdrawal by BFAD/BAI of the accreditation of the establishment's Veterinary Medical Director/Officer.
- 4.7.2 Suspension of the license to operate the veterinary drug and product establishment.
 - 4.7.3 Cancellation of the certification of product registration.
- 4.7.4 Revocation of the license to operate the veterinary drug and product establishment.

Section 5. SEPARABILITY CLAUSE

In case any provision of this A.O. is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

Section 6. REPEALING CLAUSE

All administrative orders, rules and regulations and other administrative issuances or parts thereof inconsistent with the provisions of this A.O. are hereby repealed or modified accordingly.

Section 7. EFFECTIVITY

This A.O. shall take effect fifteen days after its publication in two newspaper of general circulation.

(Sgd.) SENEN C. BACANI

(Sgd.) ALFREDO R.A. BENGZON, M.D.

Secretary of Agriculture

Secretary of Health