Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

March 13, 1989

ADMINISTRATIVE ORDER
No. 65 s. 1989

Subject: GUIDELINES ON ADVERTISEMENT AND PROMOTIONS TO IMPLEMENT THE GENERICS ACT OF 1988

Pursuant to Section 5 (c) of R.A. 6675 known as “Generics Act of 1988", Section 3 (c) of R.A 3720 known as "Food, 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 pharmaceutical products are hereby promulgated:

SECTION 1.0 DEFINITION OF TERMS

1.1 "advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any pharmaceutical product.

1.2 "Promotion" means the practice of giving temporary additional value to a brand, product, or service to achieve specific marketing objectives. "Promotion" includes the distribution of free/sample pharmaceutical products.

1.3 "Pharmaceutical product" means any pharmaceutical or biological product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or animals.

1.4 "Prescription or Ethical Drugs" are pharmaceutical products or drug preparations that are to be dispensed only upon written order of a duly licensed physician, dentist, or veterinarian for the treatment of a condition or a diagnosed disease of man or animals

1.5 “Non-prescription Drugs" or “Over-the-Counter Drugs" are pharmaceutical products or drug preparations that can be dispensed even without the written order of a duly licensed physician, dentist, or veterinarian, for or the use of consumers for the prevention or symptomatic relief of minor or self-limiting ailments.

1.6 "Mass Media" means 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 2.0 GUIDELINES ON ADVERTISEMENT AND PROMOTION BASED ON PRIOR LAWS

2.1 No person shall advertise or promote a pharmaceutical product unless such product is du1y registered by Bureau of Food and Drugs (BFAD).
2.2 All therapeutic claims for drugs, medicines or any pharmaceutical product made in advertising or promotional materials must be based on adequate scientific, pharmacological, and clinical evidence, responsible medical opinion or long experience demonstrating their safety, efficacy and therapeutic value, and must be within their therapeutic indications approved by the BFAD.
2.3 No pharmaceutical product classified by BFAD as a
Prescription or Ethical Drug shall be advertised or promoted in any form of mass media except through medical journals, publications and/or literature solely intended for medical and allied professions.

2.4 The pharmaceutical company which owns the pharmaceutical product, and its Medical Director shall be responsible and accountable for the content and form of its advertisement and promotional materials.

SECTION 3.0 GUIDELINES 0N 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 RR 6675, all advertising and promotional materials, whether print, visual or auditory, shall feature prominently the generic name of the drug product designated by BFAD. In the case of branded products, the prominence of the generic name shall be insured in all print, visual or auditory materials that feature the brand name.
3.2 Print and Static Visual Materials (e.g. Posters, Billboards)

The pertinent provisions on A.O. 55, s. 1988 55 on Requirements for Labeling materials of Pharmaceutical Products quoted hereunder shall apply with the exception that the word "label" will be substituted by "advertising and other promotional material."
"3.1.1 In all cases, the generic name shall be the prominently printed element on the [label] advertising and other promotional material defined as the one with the highest point size among the various printed elements on the [label] 'advertising and other promotional material’. It shall be enclosed exclusively by an outlined box rendered in the same color as the generic name. the background color inside the box, 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."

"3.1.2 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 of the specific chemical form of the drug needs to be indicated, this must be included inside the box but in smaller point size."

“3.1.3 If a product is identified by a brand name together with tis generic name, the following shall be required in addition to 3.1.1 and 3.1.2

"3.1.3.1 The generic name and brand name shall be rendered using the same typeface, font and color, with the generic name appearing immediately above the brand name and rendered in a point size bigger than the brand name."
"3.1.3.2 If the brand name is presented using a special typeface exclusively designed and used for it, the generic name shall be rendered in. Helvetica Medium or Universe Medium 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 will be applied, and consistent with A.O. 55 s. 1988 as amended, the generic name designated by BFQD 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 will be adopted - according to the convention of the medium.

SECTION 4.0 MONITORING QND ENFORCEMENT

4.1 The drug establishment under whose name the drug 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 medical directors.

4.2 In addition, the drug establishment may participate in other industry-wide mechanism for self or voluntary regulation. Such participation, however, shall not in any way diminish the fundamental responsibility and accountability of the drug establishment with respect to compliance with these regulations.
4.3 No prior clearance from BFQD is required for initial printing and. broadcast or dissemination of advertisement and other promotional materials for drug products.

4.4 BFAD shall monitor advertisement and promotion of drug products as well as receive

complaints regarding these. On the basis of its monitored finding or complaints, BFAD 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 will be "identified and the drug establishment responsible shall be notified. BFAD shall issue a cease and desist order stopping the further release, printing, broadcast or dissemination of the violative advertising or promotional material.

If the drug establishment wishes to contest BFAD's findings, a formal hearing shall be conducted. From the finding after the hearing, BFAD 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 as indicative of the subject drug establishment's inability to perform adequately in a manner that assures the proper use of its drug product. Under such condition and after due hearing, BFAD may impose the following sanctions:

4.7.1 Withdrawal by BFAD of the accreditation of the establishment's medical director.

4.7.2 Suspension of the license to operate of the drug-establishment.

4.7.3 Cancellation 0+ the certification of product registration.

4.7.4 Revocation of the license to operate of the drug establishment.

SECTION 5.9 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 5.0 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 7.0 EFFECTIVITY
This A.O. shall take effect fifteen days after its publication in .two' newspapers of general circulation.

ALFREDO R. A. BENGZON, M.D.

Secretary of Health