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Department of Health
OFFICE OF THE SECRETARY

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ADMINISTRATIVE ORDER
No. 113 s. 1991

SUBJECT : Guidelines on Advertisement and Promotion of Multi-active Ingredient/Fixed Dose Combination Drug Products

Section I : Definition of Terms

1.1 Fixed Dose Combination (FDC) drug products - are multi-active ingredient pharmaceutical preparations containing two or more pharmacologically active ingredients in a single formulation or dosage form.

1.2 Generic Class Name - is the single official name designated and approved to identify a combination of two or more active ingredients of FDC drug products based on their content or internationally-accepted name.

Section II : Coverage

All FDC drug products whose labelling are covered by A.O. 85 s. 1990 or A.O. 99 s. 1990 are subject to the guidelines in this A.O.

Section III: Applicability of A.O. 65 s. 1989

All relevant general and specific requirements as contained in A.O. 65 s. 1989 shall apply to the advertisement and promotion of FDC drug products.

Section IV : Specific Guidelines to Implement Advertisement and Promotion of Multi-Active Ingredient Fixed Dose Combination Drug Product

4.1 General Principle

All advertisement and promotion materials whether print, visual or auditory of all fixed-dose combination products shall feature prominently the generic names or generic class name when applicable of the FDC drug product as approved by the Bureau of Food and Drugs (BFAD). The generic names or generic class name, when applicable, shall be displayed as the most prominent feature of the advertising and promotional materials of all branded products.

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4.2 For multi-active ingredient drug products with no approved generic class name, it is required that the generic names of all active ingredients as approved by BFAD for its label, be displayed prominently.

4.3 All Therapeutic claims to be used in advertising and promotional materials shall be as stated and approved by BFAD during the product's registration.

4.4 Printed/Static Visual Materials (posters, billboards, flyers, and other printed materials)

4.4.1 The generic class name/name of active ingredients of all FDC products shall be rendered in bigger point size letters than the Brand Name and enclosed in a generic box. The font and typeface of the letters and background of the generic name shall be the same as that of the Brand Name or as approved in the product's label.

4.5 For other forms of visual materials as in television, cinema, movies, et. al., the general principle of 4.4.1 shall be followed.

4.6 For all auditory materials in radio, television or other media, the principle of the relative prominence of the generic names or generic class name of the active ingredients to that of the brand name shall be followed.

Section V : <u>Effectivity</u>

This AO shall take effect two (2) weeks after its publication in two newspapers of general circulation but mandatory compliance will be timed simultaneous with the start of mandatory generic labelling requirement for FDC drug product at retail outlets on January 1, 1992.

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