Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 April 2013

FDA Circular
No. 2013-012

SUBJECT: VALIDITY OF GENERIC LABELING EXEMPTION FOR PHARMACEUTICAL PRODUCTS

I. Background/Rationale

In 1988, the Department of Health has issued Administrative Order 55 to set the generic labeling requirements for pharmaceutical products pursuant to Republic Act No. 3720 as amended by Executive Order No. 175, otherwise known as the "Foods, Drugs and Devices, and Cosmetic Act" and Republic Act No. 6675, otherwise known as the "Generics Act of 1988."

Furthermore, Administrative Order No. 85 has been issued to address the requirements for labeling materials of certain categories of products containing two or more active ingredients. The requirements for labeling materials of categories of pharmaceutical products containing four or more active ingredients outside the coverage of A.O. 85 s. 1990 have been set upon the issuance of Administrative Order 99 s. 1990.

This Circular is issued in compliance to Section 11 of Administrative Order No. 55 s. 1988, Section V of the Implementation Details of A.O. 85 s. 1990 and Section V of Memorandum Circular No. 6 s. 1991: Implementation Details of Administrative Order 99 s. 1990 which mandate the exemption of some pharmaceutical products from the generic labeling requirements. This is also issued in line with the goal of the Food and Drug Administration to streamline the registration process of pharmaceutical products.

II. Scope

This Circular shall cover all pharmaceutical products requesting for exemption from the generic labeling requirements.

III. Objectives

This Circular aims to clarify the validity of generic labeling exemption of pharmaceutical products with the view of streamlining the registration process in the Center for Drug Regulation and Research.

IV. General Guidelines

1. For incoming initial registration of pharmaceutical products, the validity of the generic labeling exemption shall be the same as the validity of the Certificate of Product Registration except for pharmaceutical products with low volume of importation.
2. Only pharmaceutical products with low volume of importation shall request for generic labeling exemption annually due to possible changes in the volume of imported products for each year.
3. For registered pharmaceutical products, marketing authorization holders are advised to apply for generic labeling exemption with the same validity as the unexpired term of the Certificate of Product Registration.
4. The payment for generic labeling exemption shall follow the existing schedule of fees per year provided further that a fraction of a year shall be counted as one year.
5. All requests for generic labeling exemption submitted prior to the issuance of this Circular shall be given one year validity.

V. Repealing Clause

Provisions on previous circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly.

VI. Effectivity

This Circular shall take effect immediately.

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Acting Director IV, FDA