FDA CIRCULAR
No. _____

SUBJECT : Application for Labeling Compliance of Drug Products under Maximum Drug Retail Price

I. BACKGROUND/RATIONALE

Rule 31, Section 1 of the Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01 entitled the Implementing Rules and Regulations of Republic Act 9502 Otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008" stipulated that every drug product that are subject to price regulation shall reflect the retail price which shall not exceed the maximum retail price. Executive Order No. 821 s. 2009 "Prescribing the Maximum Drug Retail Prices for Selected Drugs and Medicines that Addresses Diseases the Account for the Leading Causes of Morbidity and Mortality", 5 drug molecules or 27 drug formulas are subjected to price regulation

By virtue of E.O. No. 104 s. 2020 "Improving Access to Healthcare through the Regulation of Prices in the Retail of Drugs and Medicines" the drug product under price regulation are further expanded to 122 drug molecules or 205 drug formulas. On 12 May 2020, in consideration to the COVID-19 pandemic, a Memorandum was released by the DOH for the compliance of labeling materials for MRP medicines until 02 June 2021.

To reduce the regulatory burden in the application and approval of the inclusion or update of the MRP or the Maximum Drug Retail Price (MDRP) statement to the labeling materials of drug products, this Circular is hereby issued.

II. OBJECTIVES

This Circular is issued to:

1. To provide a streamlined and rational application process for the change and/or update of labeling materials in compliance to R.A. No. 9502, E.O. 821 s. 2009 and E.O. No. 104 s. 2020.
2. To require all drug product under Initial (and Monitored Release) to bear the MDRP statement upon filing for application.

III. SCOPE

This shall be applicable to all drug products listed under R.A. No. 9502, E.O. 821 s. 2009 and E.O. No. 104 s. 2020. for price regulation.

IV. GUIDELINES

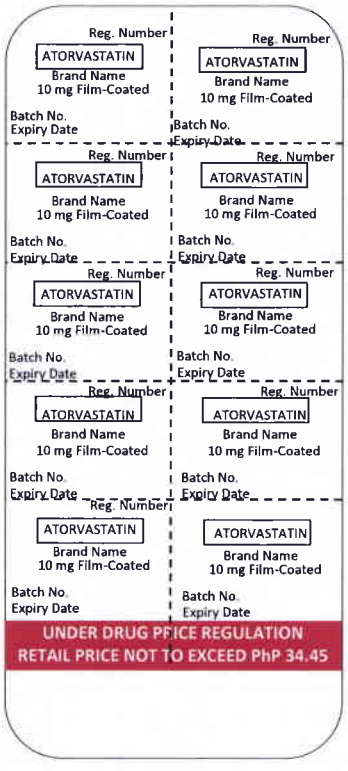
A. The format and guidelines of the MDRP statement shall follow Section VI (B) (7) of Administrative Order (AO) No. 2016-0008 "Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug products for Human Use".

Example:

UNDER DRUG PRICE REGULATION
RETAIL PRICE NOT TO EXCEED (price)

The MDRP statement shall be indicated on the labeling of the minimum pack and the outer presentation of drugs.

Example:



B. Applications for the change or inclusion of the price or MDRP statement shall follow the Minor Variation-Notification [MiV-PH-N1] as per FDA Circular No. 2016-017 "Additional Post-Approval Changes for Pharmaceutical Products". The following documentary requirements shall be submitted:

1. Notarized Application Form – Notification for Minor Variation/s of Registered Pharmaceutical Product (FC No. 2020-026, Annex C)
2. Currently approved labeling materials,
3. Proposed labeling materials with annotations, and
4. Proof of payment

C. Exhaustion of old labeling materials
Deadline of use and exhaustion of old labeling materials shall only be allowed until 02 June 2021 only, regardless of the date of filing of post-approval change. No extension of exhaustion shall be given.

D. Drug products covered under this Circular that shall be for initial registration (including Monitored Release) shall bear the MDRP statement.

V. SANCTIONS

Violations of this Circular shall warrant the application of the penalties under the applicable provisions of Republic Act No. 9711 and Republic Act No. 9502 and the Implementing Rules and Regulations thereof.

VI. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following its publication in a newspaper of national circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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Keywords	Maximum Retail Price; Maximum Drug Retail Price; MRP; MDRP
Related Issuances, laws, directives from other government agencies	Republic Act No. 9502 Executive Order No. 104 s. 2020 Administrative Order No. 2016-0008 FDA Circular No. 2014-008 FDA Circular No. 2016-017