Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-015

21 APR 2020

SUBJECT: **Interim Measures to Ensure Access to Vitamin Drug Products during the Coronavirus Disease 2019 (COVID-19) Pandemic**

I. RATIONALE

With the implementation of the Enhanced Community Quarantine (ECQ) as a measure to control the spread of the COVID-19, certain industries were required to operate in its skeletal force or were forced to cease operations until the ECQ is lifted.

Primarily hit establishments are local drug product manufacturing industries with or without packing/repacking activity/ies and importers. Increase in demands of purchase of certain essentials medicines, particularly of vitamin drug products lead to raw material and packaging deficiencies.

To ensure continuous access of consumers to vitamins, without compromising the quality of the drug products, this Circular is hereby established.

II. OBJECTIVE

This Circular aims to provide guidance to the following:

1. Guidance for initial registration of vitamin drug products of alternative packaging to its currently registered counterpart;
2. Temporary marketing authorization of vitamin drug products with different blister or capsule color; and
3. Temporary marketing authorization of vitamin drug products without its secondary packaging.

III. SCOPE AND COVERAGE

This Circular covers all locally manufactured and imported bulk registered vitamin drug products for packing/repacking under the Household Remedy (HR) and Over-the-Counter (OTC) classification.

IV. GUIDELINES

A. Initial Registration

The use of a different packaging material as to the current registered packaging materials shall require an initial registration application and shall follow the complete requirements under Administrative Order (A.O.) No. 67 s. 1989 "Revised Rules and Regulations on Registration of Pharmaceutical Products", A.O. No. 2016-008 "Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use", and other relevant issuances.