Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-015-C

SUBJECT : EXTENSION OF THE EFFECTIVITY OF FDA CIRCULAR NO. 2020-015, AS AMENDED, ENTITLED "INTERIM MEASURES TO ENSURE ACCESS TO VITAMIN DRUG PRODUCTS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC"

In the interest of service and due to the continuing Public Health Emergency of International Concern, the effectivity of FDA Circular No. 2020-015-B entitled "Further Amendment to FDA Circular No 2020-015, Subject: Interim Measures to Ensure Access to Vitamin Drug Products during the Coronavirus Disease 2019 (COVID-10 Pandemic)" is hereby extended until 31 December 2021.

For the information and guidance of the public.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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.

Registration applications without stability data up until 12 months shall comply with the following conditions and additional requirements:

1. Conditions:
   a. The drug product being applied for alternative packaging material must have the following:
      i. valid CPR; and
      ii. same formulation, manufacturing procedure, technical specifications and quality control tests such as assays for both raw materials and finished product.
   b. The drug product which will be approved under this Circular shall be given an interim shelf-life of 6 months with a CPR validity of only two (2) years.
   c. The drug product shall be approved under the same brand name and same entities as indicated in its reference counterpart in Section IV, A, 1, a of this Circular. A different registration number shall be given.
   d. For registered Identical Drug Products that would wish to apply an initial registration under this Circular, a Principal CPR (PCPR) counterpart must first be registered.

2. Additional Requirements:
   a. A commitment letter to submit the stability data within one year upon the issuance of the CPR.
   b. Copy of valid Certificate of Product Registration (CPR) of its reference counterpart in Section IV, A, 1, a of this Circular.
   c. Currently approved labeling materials of the reference counterpart and proposed labeling materials of the proposed packaging materials.
   d. Actual representative sample with corresponding Certificate of Analysis.

3. Post-Approval Compliance
   The Stability Data for two (2) succeeding Commercial Batches shall be submitted within the CPR validity. Full revalidation shall be given for satisfactory stability data.

B. Certification of Temporary Capsule or Blister Color Use

1. Vitamin drug products that shall use a temporary capsule or blister must secure a Certification from this Office.
2. The following requirements shall be submitted at the FDAC Letters:
   a. Letter of Request for use of Temporary Capsule or Blister. For each proposed color or blister, a different request shall be made. Each request shall be applicable for only one drug product (hard and soft copy)
   b. Copy of valid CPR and its amendments
   c. Currently approved and proposed specifications of the capsule or blister material
   d. Pictures of the currently approved and proposed capsule or blister material, whichever is applicable.
   e. Representative samples with corresponding Certificate of Analysis
   f. Payment of Php 500.00 + LRF

3. The certification shall be valid only until the ECQ. No further extension shall be allowed.

C. Certification for Bundling

1. Vitamin drug products that shall be marketed without its secondary packaging and instead thru bundling shall be required to secure a Certification from this Office.
2. Copy of valid CPR and its amendments
3. The following requirements shall be submitted at the FDAC Letters:
   a. Letter of Request for use of bundling.
   b. Photo of bundling (Blister or Bottle + product information leaflet)
   c. Payment of Php 500.00 + LRF
   d. Representative samples with corresponding Certificate of Analysis of the bundled product
4. The certification shall be valid only until the ECQ. No further extension shall be allowed.

D. Application Process

1. There shall be no need for the scheduling of submission of registration applications under this Circular. Submission shall be made in accordance with FDA Circular No. 2020-006-A "Amendment to FDA Circular No. 2020-006 Entitled "Guidance for Applications and Transactions at the Food and Drug Administration in Light of the Community Quarantine Declaration" issued on 17 March 2020".
2. Requests for Certifications under Sections B and C of this Circular shall be submitted at FDAC Letters.

V. REPEALING CLAUSE

In the event that any provision or part of this Circular is declared unauthorized or rendered invalid by any court of law, those provisions not affected by such declaration shall remain valid and effective.

VI. EFFECTIVITY

This Circular shall take effect immediately for the duration of the declared quarantine for the management of the COVID-19 situation, and the effectivity of this Circular shall likewise be automatically lifted once the imposed quarantine is lifted.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 AUG 2020

FDA CIRCULAR
No. 2020-015-A

SUBJECT: **Amendment to FDA Circular No. 2020-015 entitled "Interim Measures to Ensure Access to Vitamin Drug Products during the Coronavirus Disease 2019 (COVID-19) Pandemic"**

On 21 April 2020, FDA Circular No. 2020-015 entitled "Interim Measures to Ensure Access to Vitamin Drug Products during the Coronavirus Disease 2019 (COVID-19) Pandemic" was issued. The said Circular provided interim guidelines for the registration and certification of vitamin products in response to the shortage of supplies in the market brought upon by the limited production and supplies due to the enhanced community quarantine (ECQ).

Due to the regular updates to the quarantine status of the different cities and municipalities, the provisions of this Circular may still deemed be applicable and necessary by the public's interest.

In view of the foregoing, the provisions of FDA Circular No. 2020-015 shall be effective until 31 December 2020, subject for extension upon the review of this Office.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-015-B

22 SEP 2020

SUBJECT: **Further Amendment to FDA Circular No. 2020-015 entitled "Interim Measures to Ensure Access to Vitamin Drug Products during the Coronavirus Disease 2019 (COVID-19) Pandemic"**

On 21 April 2020, FDA Circular No. 2020-015 was issued to provide interim measures to ensure access to vitamin drug products during the Coronavirus Disease 2019 (COVID-19) Pandemic. Subsequently, FDA Circular No. 2020-015-A was issued to extend the validity of said Circular.

Considering that there are regular updates on the quarantine status of different localities in the country, the validity of the provisions of this Circular should remain unaffected to ensure access to vitamin drug products during the COVID-19 pandemic.

Hence, FDA Circular No. 2020-015 shall be valid until 31 December 2020, regardless of the level of the imposed quarantine restriction, and subject to extension upon the review of this Office.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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