

**ORDER
OF AUTOMATIC RENEWAL**

USEC. ROLANDO ENRIQUE DOMINGO, DPBO

Officer-In-Charge

Food and Drug Administration

Civic Drive, Filinvest Corporate City

Alabang, Muntinlupa City

GREETINGS:

The Authority takes due notice of the summary or breakdown of pending applications with the Center for Food Regulation and Research (CFRR)¹ and Center for Drug Regulation and Research (CDRR)², which your good office submitted. Based on your representation and manifestation during our meetings on 02 and 05 September 2019, the applications classified as Automatic Renewal under CFRR and Automatic Renewal under CDRR are purely ministerial. Furthermore, Section 3 (A) (2) and 3 (B) (2) of Book II, Article I of the Implementing Rules and Regulations of R.A. 9711 or the *Food and Drug Administration (FDA) Act of 2009* provides, to wit:

BOOK II

ARTICLE I

Licensing of Establishments and Registration of Health Products

Sec. 3. Approval of License of Establishments and Registration of Health Products.

A. License to Operate.

XXX

XXX

XXX

(2) Renewal of License. No application for renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the LTO when the following conditions are satisfied:

¹ Copy of the list of pending applications with the CFRR as of July 31 is hereto attached as **Annex "A"**.

² Copy of the list of pending applications with the CDRR as of July 31 is hereto attached as **Annex "B"**.



- i. The application is filed before the expiration date of the license;*
- ii. The prescribed renewal fee is paid upon filing of the application; and*
- iii. A sworn statement indicating no change or variation whatsoever in the establishment is attached to the application.*

XXX XXX XXX

For applications for renewal filed within one hundred twenty (120) days from its original expiry, the LTO shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

XXX XXX XXX

B. Authorization/Certificate of Product Registration.

XXX XXX XXX

(2) Renewal of Registration. No application for renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the CPR when the following conditions are satisfied:

- i. The application is filed before the expiration date of the registration;*
- ii. The prescribed renewal fee is paid upon filing of the application; and*
- iii. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.*

XXX XXX XXX

For applications for renewal filed from within one hundred twenty (120) days from its original expiry the CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

XXX XXX XXX

By virtue of Section 10 of R.A. 11032 or the *Ease of Doing Business and Efficient Government Service Delivery Act of 2018*, in relation to Section 4 of Rule VIII of its Implementing Rules and Regulations, the Authority hereby **DECLARES THE COMPLETENESS** of all the pending applications, which have submitted the complete

documentary requirements pursuant to the above rules and have paid the required fees until **08 August 2019** or **twenty (20) working days** immediately prior to the issuance of this Order, classified as follows:

A. CFRR	
Kind of Application	Total:
1. E-Registration	
1.2. Renewal	1081
2. Licensing	
2.2. Renewal	27
B. CDRR	
Automatic Renewal	1818
PCPR	199

Consequently, the foregoing applications are deemed **AUTOMATICALLY APPROVED** and/or **AUTOMATICALLY RENEWED** by operation of law, as the case may be. In view thereof, the Food and Drug Administration is hereby **ORDERED** to **ISSUE** the corresponding permits, licenses, or any other certification for the foregoing applications. The issuance of this Order is without prejudice to your conduct of the necessary Post Audit Compliance and the filing of criminal charges against parties who will be found to have committed an act of misrepresentation or false entry in their Sworn Statement/ Undertaking and the imposition of administrative fines including but not limited to suspension, cancellation or revocation of certificate and license as provided by your rules.

SO ORDERED.

Makati City, 09 September 2019.

Recommended By:


ATTY. ERNESTO V. PEREZ, CPA
Deputy Director General

Approved By:


ATTY. JEREMIAH B. BELGICA, REB, EnP
Director General