Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY No. 2019-305

20 SEP 2019

TO : **ALL FDA STAKEHOLDERS AND GENERAL PUBLIC**

SUBJECT : **INFORMATION ON THE ANTI-RED TAPEAUTHORITY (ARTA) ORDER OF AUTOMATIC RENEWAL DATED 09 SEPTEMBER 2019**

The Food and Drug Administration (FDA) fully supports the implementation of the Republic Act (RA) No. 11032, otherwise known as the *Ease of Doing Business and Efficient Government Service Delivery Act of 2018*. Since its enactment into law, multiple initiatives and reforms are being undertaken by the FDA in order to deliver quality and efficient services to its clients and the public it protects.

In light of the ARTA Order of Automatic Renewal issued on 09 September 2019 by ARTA Director General Atty. Jeremiah B. Belgica, REB, EnP, the FDA shall implement the said Order, as stated:

> *"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 following conditions for Automatic Renewal of License to Operate (LTO) and Certificate of Product Registration (CPR) shall be met, as stated in the RA No. 9711 otherwise known as the *Food and Drug Administration (FDA) Act of 2009* and its Implementing Rules and Regulations:

a. The application is filed before the expiration date of the license;
b. The prescribed renewal fee is paid upon filing of the application; and
c. Sworn statement indicating no change or variation whatsoever in the establishment is attached to the application.

However, this does not preclude FDA from conducting Post-Marketing Surveillance activities on establishments and health products.

For public health reasons, any company found to have committed misrepresentations, false entries or claims against the Affidavit of Undertaking submitted in the Automatic Renewal application shall be subject to administrative and criminal liabilities, provided for by the RA No. 9711, which includes but not limited to suspension, cancellation, or revocation of their License to Operate and/or Certification.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

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Attachment: ARTA Order of Automatic Renewal Dated 09 September 2019