

**PEZA - FDA**  
**MEMORANDUM OF AGREEMENT**  
**JUNE 2014**

PHILIPPINE ECONOMIC ZONE AUTHORITY  
Roxas Boulevard corner San Luis Street,  
Pasay City  
Website: <http://www.peza.gov.ph>

and

FOOD AND DRUGS ADMINISTRATION  
Civic Drive, Filinvest Corporate City, Alabang,  
Muntinlupa City  
Website: <http://www.fda.gov.ph>

**KNOW ALL MEN BY THESE PRESENTS:**

This Memorandum of Agreement executed and entered into this 30<sup>th</sup> of June 2014 in Manila, Philippines by and between:

The Philippine Economic Zone Authority, created and duly organized pursuant to Republic Act No. 7916 or "The Special Economic Zone Act of 1995" as amended, with principal office address at PEZA Bldg., Roxas Blvd. corner San Luis St., Pasay City, represented by its Director General, Atty. Lilia B. De Lima, hereinafter referred to as "PEZA".

~and~

The Food and Drugs Administration created and duly organized pursuant to Republic Act 9711 or the "Food and Drug Administration Act of 2009" and its IRR which further amended Republic Act No. 3720 otherwise known as the "Food, Drugs and Devices and Cosmetic Act" signed August 18, 2009 and its IRR, with office address at Civic Drive, Filinvest Corporate City, Alabang, City of Muntinlupa, represented by its Director General, Dr. Kenneth Y. Hartigan-Go, hereinafter referred to as "FDA".

**WITNESSETH:**

**WHEREAS**, there is the expressed concern of PEZA-registered companies on the expeditious release of FDA-related authorizations parallel to the timeframe with other ASEAN countries.

**WHEREAS**, PEZA and FDA agreed to streamline the current critical processes in licensing, inspection and registration of PEZA-registered enterprises exporting or importing their products.

**WHEREAS**, PEZA and FDA agreed that PEZA shall assist its registered enterprises in pre-processing of application of FDA-related authorizations.



**WHEREAS**, Section 13 of Republic Act No. 7916, otherwise known as the “The Special Economic Zone Act of 1995” as amended, provides that PEZA shall register, regulate and supervise the enterprises in the ecozones in an efficient and decentralized manner and shall coordinate with appropriate government agencies for policy and program formulation and implementation;

**WHEREAS**, Republic Act No. 9711 known as the “Food and Drug Administration (FDA) Act of 2009” mandates the FDA to regulate the manufacture, distribution, importation, exportation, sale, offer for sale, transfer, marketing, advertisements, sponsorship and promotion of health products, as defined by RA 9711, through issuances of authorization, such as License to Operate, Certificate of Product Registration, and special permits;

**WHEREAS**, the FDA has the following Centers, namely: The Center for Drug Regulation and Research, The Center for Food Regulation and Research, The Center for Cosmetics Regulation and Research, and The Center for Device Regulation, Radiation Health, and Research, other Offices, that implement systems and processes for application, evaluation and issuance of authorization, among other regulatory activities, such as post-market surveillance and monitoring.

**WHEREAS**, Section 36 of Republic Act No. 7916 provides that there shall be established in the ecozone, a one stop shop center to facilitate the registration, licensing and issuance of permits to ecozone enterprises. Thus, as a matter of policy, PEZA shall enter into Memorandum of Agreement with the FDA for an integrated and simplified implementation of licensing, registration, certifications, compliance monitoring and development control over PEZA registered enterprises that manufacture food, medical devices, cosmetics and household hazardous substances and other regulated entities and products.

**WHEREAS**, the PEZA through its designated units, has the capability to assist the FDA in facilitating the processing and issuance of licenses and certifications (notification and application) for industries located inside the economic zones;

**NOW, THEREFORE**, for and in consideration of the above premises, hereby agree and declare as follows:

**I. GENERAL PROVISIONS**

1. The FDA shall collaborate with PEZA in formulating and implementing rules and regulations to ensure compliance by all affected PEZA registered enterprises with the provisions of Republic Act No. 9711, otherwise known as the Food and Drug Act of 2009 and Republic Act No. 3720, otherwise known as the Food, Drugs and Devices, and Cosmetic Act, and other pertinent laws, policies, guidelines, rules and regulations.

2. The PEZA and the FDA shall jointly conduct training courses and workshops, information dissemination, inspection, sampling of products, and other activities as necessary and as permitted under the law for the implementation of pertinent laws, policies, guidelines, rules and regulations to ensure the safety, efficacy or quality of health products under the jurisdiction of the FDA.

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## II. RIGHTS AND OBLIGATIONS OF THE FDA

The FDA shall:

1. Provide the PEZA with copies of all relevant rules, regulations and procedures on the implementation of the FDA Act of 2009 and its IRR, and other relevant rules and regulations implemented and enforced by the FDA to ensure the safety, efficacy or quality of health products that are manufactured, distributed, imported, exported, traded, advertised, promoted, sold or offered for sale, and transported;
2. Collaborate with PEZA in drafting and review of policies, guidelines, rules, regulations, protocol and procedures on licensing, inspection, registration, advertisement and promotion, monitoring and control of establishments or products under the jurisdiction of the FDA;
3. Train PEZA officials/staff on the implementation of the FDA Act of 2009 and its implementing rules and regulations, and all relevant laws, rules and regulations;
4. Assist the PEZA on the establishment and operationalization of its designated unit to pre-process the complete and correct requirements for a license to operate and product registration or notification applications prior to submission to FDA;
5. Establish an express lane and identify a reasonable processing time to evaluate and approve PEZA-registered enterprise applicants for FDA permit and/or licenses;
6. Expedite the issuance of FDA-related authorizations of PEZA-registered enterprises;
7. Conduct inspections in coordination with PEZA and post-market surveillance or monitoring of establishments or products on PEZA-registered companies in coordination with PEZA;
8. Inform the PEZA on the status of registered enterprises' compliance with the terms of their licenses / certification within their jurisdiction relative to any administrative or legal measures/ remedies that may be necessary to enforce the FDA Act;
9. Issue a moratorium for a period of one (1) year on licensing of establishment and registration of health products for existing PEZA-registered enterprises after the signing of this MOA, while ensuring that the economic activities in PEZA are unhampered during the same period; and,
10. Provide an FDA point person/ contact person or unit for ease of communication and coordination with PEZA.

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### III. RIGHTS AND OBLIGATIONS OF THE PEZA

The PEZA shall:

1. Assist the FDA in ensuring compliance of PEZA-registered enterprises to FDA Act of 2009 and other rules and regulations in the respective economic zones;
2. Provide the necessary administrative assistance in the conduct of training courses and workshops conducted by the FDA to implement the provisions of the FDA policies, guidelines, rules and regulations to ensure the safety, efficacy or quality of health products;
3. Support the FDA in ensuring the submission of complete and correct requirements during pre-processing of applications of PEZA-registered enterprises for FDA-related authorizations;
4. Assist the FDA in ensuring compliance of PEZA registered enterprises with the FDA laws, rules and regulations;
5. Collaborate with FDA in drafting and review of FDA policies, guidelines or procedures that may affect the implementation of PEZA programs and projects;
6. Cooperate with FDA on matters on enforcement and compliance with FDA Act of PEZA-registered enterprises; and,
7. Identify, assign and authorize the PEZA designated units which will pre-process the FDA requirements and other documents.

### IV. AMENDMENTS

1. Any modifications of this MOA or any part thereof shall be upon execution of a written instrument duly signed by both parties; and,
2. Should circumstances necessitate the revision of the agreements embodied in this MOA, the concerned parties shall, prior to such revision, grant a reasonable grace period of implementation.

### V. EFFECTIVITY

This Memorandum of Agreement shall take effect upon execution hereof and remain enforced until both parties decide to terminate the same in accordance with the provisions of this MOA.


**VI. TERMINATION**

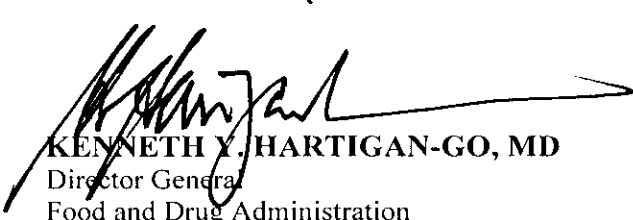
This MOA may be terminated:

- i. Upon failure of either party to perform and observe the terms and conditions of this MOA;
- ii. Delay or failure by a party to perform its obligations under this MOA unless the cause or circumstance is beyond its control.

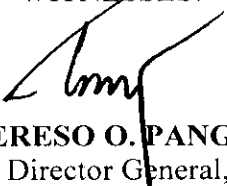
Upon mutual agreement of the parties, this MOA may be terminated or any part thereof be suspended or deferred, with notice to the other party six (6) months prior to the intended termination/suspension.

Provided, that the agreement is reduced to writing and signed by the parties.


  
**LILIA B. DE LIMA**  
Director General  
Philippine Economic Zone Authority  
Department of Trade and Industry

  
**KENNETH Y. HARTIGAN-GO, MD**  
Director General  
Food and Drug Administration  
Department of Health

WITNESSES:

  
**TERESO O. PANGA**  
Deputy Director General, PEZA

  
**ARIEL VALENCIA, MD**  
Deputy Director General, FDA





**ACKNOWLEDGEMENT**

REPUBLIC OF THE PHILIPPINES

**PASAY CITY**  
Manila

S.S

BEFORE ME, <sup>JUL 09 2014</sup> this day Month, 2014 at Manila, Philippines, personally appeared:

<b>Name</b>	<b>CTC / Passport Number</b>	<b>Date / Place of Issue</b>
KENNETH Y. HARTIGAN-GO		
LILIA B. DE LIMA		

Known to me and to me known to be the same persons who executed the forgoing instrument, and they acknowledgement to me that the same is their free act and deed and that of the agency or entity which they respectively represent.

This instrument consists of six (6) pages, including the page on which this acknowledgement is written; all pages hereof had been signed by the parties executing this instrument and their witness, and sealed with my notarial seal.

**IN WITNESS WHEREOF**, I have affixed my signature the day, year, and place above written.

*Rose Vincennes Sy*  
**ROSE VINCENNES SY**  
**NOTARY PUBLIC FOR PASAY CITY**  
COMMISSION NO. 13-11 UNTIL DEC. 31, 2014  
ATTY. ROLL NO. 50343  
IDP NO. 950452/1-3-14/ CAM. SUR  
PTR NO. 36/4040/1-3-14/PASAY CITY

*Sub-*  
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