Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

11February 2014

FDA CIRCULAR
No. 2014 003

TO: All Establishments Seeking to, or Currently Engaged in the Manufacture, Import, Export, Distribution and Retail of Health Products in the Philippines; the Bureau of Customs, the Department of Trade and Industry, and other agencies requiring documents issued by the Food and Drug Administration

FROM: **KENNETH Y. HARTIGAN-GO, MD**
Director
Food and Drug Administration

SUBJECT: **Filing and Receiving of Registration, Licensing and Other Applications Using the Integrated Application Form**

I. Rationale

Republic Act no.9485, the Anti-Red Tape Act of 2007, was enacted to improve efficiency in the delivery of government services and to establish effective practices aimed at the prevention of graft and corruption in government. Government agencies and offices are mandated to promote transparency with regard to the manner of transacting with the public. Further, these measures shall encompass a program for the adoption of procedures to reduce red tape and expedite transactions in government. Section 5 of the same lawstates that all offices and agencies which provide frontline services shall undergo evaluation and improvement of their transaction systems and procedures and re-engineer the same if deemed necessary to reduce bureaucratic red tape and processing time.

Section 3 of Republic Act no. 9711, the Food and Drug Administration Act of 2009, has declared it "a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to:" … "help establish and maintain an effective health products regulatory system…". Section 5 of the same law amending Section 4 of Republic Act no. 3720 provided the FDA with the authority "to prescribe standards, guidelines, and regulations with respect to information, advertisements, and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products as covered in this Act;".

II. Objectives

With the intention of promoting accountability and transparency through greater use of information and communication technologies,the Integrated Application Form is hereby adopted to simplify and streamline the requirements for FDA authorization, and the application process dependent on the same form is prescribed.

III. Scope

This issuance shall cover FDA-regulated products and establishments under the Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR) and the Center for Cosmetic Regulation and Research (CCRR).

The following authorizations are served by the Integrated Application Form:

1) License to Operate, including initial, renewal, compliance, and amendments;
2) Certificate of Product Registration, including initial, renewal, amendments, re-application, Principal CPR, and Certificate of Listing of Identical Drug Product;
3) Promo and Advertisement Permits;
4) Certificate of Free Sale;
5) Export Certificate;
6) Certificate of Pharmaceutical Product;
7) Generic Labeling Exemption;
8) Certificate of Compliance with Good Manufacturing Practice (GMP);
9) Certificate of Compliance with Hazard Analysis and Critical Control Points (HACCP);

IV. Guidelines

A. Principles

1. The Integrated Application Form is the primary documentary requirement for any authorization issued by the FDA.
   a. The Integrated Application Form satisfies the requirement for any of the following documents required by any Center of the FDA for purposes of licensing, registration, or other authorization: application letter, application form, petition letter, petition form, declaration form, electronic copy affidavit, and the affidavit of undertaking.
   b. The assessment of fees is incorporated into the form and no separate assessment form shall be further required.
   c. A completed Integrated Application Form is required for a Document Tracking Log to be issued by the FDA.

2. The Integrated Application Form is of an electronic file format,publicly accessible, able to be accomplished independent of guidance by an FDA officer, at a pace and in a facility determined by the applicant;
   a. The electronic file of the Integrated Application Form is comprised of four documents:
      i. Application Form (ANNEX I) ;
      ii. Petition Form for License Applications (ANNEX II);
      iii. Declaration Form for Non-Drug Registration Applications (ANNEX III), and;
      iv. Declaration Form for Drug Registration Applications (ANNEX IV);

b. For licensing application, the Integrated Application Form is a two-page document: the first being the Application Form and the second a Petition Form;
c. For registration application, the Integrated Application Form is a two page-document: the first being the Application Form and the second a Declaration Form;
d. For all other applications, the Integrated Application Form is a one-page document comprising of the Application Form.
e. Only the Petition and Declaration Forms require notarization.

3. All information and documents submitted to the FDA in satisfaction of any authorization will be collected and verified.

4. The applicant establishment, represented by the individuals signing the application form, agrees to be bound to the terms of the petition and declaration forms as appropriate.

5. Hardcopies shall no longer be required upon submission, including original authorization;
   a. All copies of original authorization issued by the FDA shall be surrendered prior to release of a renewed authorization at the Central Releasing;
   b. Hardcopies of the requirements in support of an application shall always be made available and submitted upon request of the Center in the process of evaluation.
   c. Hardcopies of original documents including Certificates of Free Sale are not required to be submitted but must be presented to officers of the FDA during onsite audits.

B. Requirements

The following documents are expected to be presented at the point of receiving during the appointed schedule:

1. Complete application documentaryrequirements in a preferred document format stored in a USB device:
   a. Include the Integrated Application Form in the format it was accomplished, and a scanned copy of the signed and notarized form as appropriate.
   b. Store all files relevant to a single application in a single folder labeled with the document tracking number issued by the FDA;
   c. Each required document comprising a single application must be submitted as an independent file and named as the requirement that it satisfies:
      E.g. 1) the PDF of the Certificate of Free Sale is named as 'Certificate of Free Sale';
      E.g. 2) the PNG of the floor plan of the ground floor of a facility is named as 'Floor Plan for the Ground Floor';
   d. For multiple applications, each application must have a separate folder;
   e. Preferred document formats:

i. PDF;
ii. Word 97-2003;
iii. PNG for image files;

f. Images are preferred to be at least 150 dpi.

2. Two (2) hardcopies of the Document Tracking Log issued by the FDA

3. Two (2) hardcopies of the accomplished and duly notarized Integrated Application Form signed by the authorized representative and the approving authority of the applicant company.

4. Original copy(ies) of proof of payment of appropriate fees and charges (machine validated OnColl payment slip or the original copy of the official receipt issued by the FDA Cashier);
   a. One copy of the Oncoll payment slip will be collected by the Central Receiving for endorsement to Accounting.

5. One (1) representative sample in commercial presentation for registration application of only the following:
   a. Pharmaceuticals (contained in a bubble wrap package);
   b. Food supplements; and
   c. Household pesticides only.

C. Procedure

1. Download the Integrated Application Form from the FDA website (www.fda.gov.ph).

2. Fill-up the Integrated Application Form with appropriate, complete and true information.

3. Send application email to pair@fda.gov.ph.
   a. Up to ten (10) application details may be sent in a single email.
   b. Subsequent email communication will be through the email used to submit the application form to FDA, unless other channels are indicated by the applicant.

4. A Document Tracking Log (Annex V) is sent via email to the applicant within two (2) working days of receipt of application form by FDA.
   a. A separate Document Tracking Log (DTL) will be issued for every application.
   b. The Routing Slip Number (RSN or Tracking Number) indicated in the DTL is the unique application identifier that will be used in payment, follow-ups and publication.
   c. The schedule of submission of application will be indicated in the DTL.

5. Scheduling
   a. Schedule will be set within ten (10) working days of receipt of application form through pair@fda.gov.ph.
   b. Applications will be received daily.

c. A daily quota on the number of applications scheduled for submission will be set by the FDA.
d. The FDA reserves the authority to schedule the receipt of applications.

6. Payment Collection
   a. Land Bank of the Philippines
      i. Proceed to any LBP branch for payment;
      ii. Fill-out an OnColl Payment Slip (see Annex VI)

Table 1 FDA Accounts

Center for Cosmetics Regulation and Research	0392-2220-06
Center for Device Regulation and Radiation Health Research	0392-2220-30
Center for Drug Regulation and Research	0392-2220-14
Center for Food Regulation and Research	0392-2220-22

      iii. Present the Oncoll Payment Slip to LBP tellers together with the printed application form and document tracking log and the corresponding cash/ check payment.
      iv. Bank service fee of forty pesos (Php 40.00) for every payment transaction made shall be shouldered by the clients.
      v. A validated OnColl Payment Slip and assessment form will be returned by the teller as proof of payment in lieu of the issuance of an Official Receipt.
      vi. For verification/ posting of payment receipt, a scanned copy of the validated OnColl Payment Slip should be sent through email to accounting@fda.gov.ph.

   b. FDA Main Office Cashier
      i. Proceed to the Cashier for payment;
      ii. Present the application form and document tracking log and the corresponding cash/ check payment;
      iii. An Official Receipt is issued by the Cashier as proof of payment.
      iv. Only applicants scheduled to be received for the day will be accommodated by the Cashier, otherwise proceed to any LBP branch for payment.

7. Receiving
   a. Only applicants scheduled for the day will be received;
   b. The applicant proceeds to the FDA Central Receiving on the schedule indicated in the Document Tracking Log;
   c. The documents identified in Section B. Requirements, Chapter IV. Guidelines of this issuance are submitted;
   d. The FDA downloads the electronic copy of the application documents from the USB device of the applicant;
   e. The proof of payment is presented;
   f. If payment is made through the Land Bank of the Philippines, a machine-validated copy of the On-Coll Payment Collection Slip is collected;

g. The Central Receiving returns the USB device of the applicant with the updated Document Tracking Log indicating the receipt of the application;

8. Reschedulingafter Forfeit of Schedule
   a. The following conditions shall render the schedule for submission forfeit:
      i. Incomplete requirements during submission, including failure to provide proof of payment;
      ii. Failure to appear as scheduled;
      iii. Failure to complete transfer of electronic application and supporting documents from applicant to FDA;
      iv. Other situations that lead to the failure of the completion of the receiving process within schedule.
   b. Applicants with forfeited schedules must send to pair@fda.gov.ph the RSN of the original schedule and will be processed for rescheduling.
   c. Only forfeited schedules may be rescheduled.

V. Repealing Clause

Memorandum Circular number 2013-0038 is hereby repealed.
Any regulation or provision inconsistent with the terms of this Circular is repealed or modified accordingly.

VI. Saving Clause

If any provision or term of this Circular is declared invalid by any court or tribunal, such declaration shall not affect the remaining provisions of this Circular.

VII. Effective Date

a. The Integrated Application Form will be available for download from www.fda.gov.ph starting 17 February 2014.
b. Only the Integrated Application Form will be accepted for schedule requests starting 3March 2014.

This Circular shall take effect 17 February 2014.

Department of Health
Food and Drug Administration
ANNEX I

APPLICATION FORM

This is the application form. Without the appropriate petition or declaration form, this application may be rejected.

APPLICATION FORM STATUS

GENERAL INFORMATION:	PROCEED
ESTABLISHMENT INFORMATION:	PROCEED
PRODUCT INFORMATION:	PROCEED
SUPPORTING INFORMATION:	PROCEED
SOURCES & CLIENTS:	PROCEED
APPLICANT INFORMATION:	PROCEED

PAYMENT DETAILS

Amount Due:	Php	7,575.00
Fee :	Php	7,500.00
Legal Research Fee :	Php	75.00
Surcharge :	Php	-
OR Number :		
Date Paid:		
Computation Valid Until:		30 September, 2014

Food and Drug Administration PHILIPPINES

Document Tracking Number
12345678901234

Description (Optional):
FOR DEMONSTRATION PURPOSES ONLY

1 GENERAL INFORMATION — PROCEED

1.1 Product Center: Drug
1.2 Authorization: Product Registration
1.3 Type: Renewal

1.4 Current License Number: 123-456-789
1.4.1 Expiry Date: 30-Jul-14
Your License will expire in 175 days.

1.5 Current Registration Number: 123-456-789
1.5.1 Expiry Date: 30-Sep-14
Your Registration will expire in 237 days.

1.6 Are there amendments or variations with your current authorization? Yes
Declare Appropriate Amendments

1.6.1 Type of Amendment 1: Change of Importer/ Distibutor
1.6.2 Type of Amendment 2: Additional Package Size
1.6.3 Type of Amendment 3: Change of Importer/ Distibutor

NCR and other region(s)
50 K and below
Promo Title!

2 ESTABLISHMENT INFORMATION — PROCEED

2.1 Primary Activity: Processor
2.2 Name of Establishment
Demonstration Establishment
2.3 Declared Capital (PhP): 5 M to below 10 M
2.4 Tax Identification Number: 123-456-789
2.5 Office Address — 2.5.1 Region: NCR
Office Address of Establishment
2.6 Warehouse Address — 2.6.1 Region: IVA
Warehouse Address of Establishment
2.7 Plant Address — 2.7.1 Region: ARMM
Plant Address of Establishment
2.8.0 E-mail Address: emailaddress@establishment.com
2.8.1 Contact Detail 1 — Landline: 1234567
2.8.2 Contact Detail 2 — Mobile: 1234567
2.8.3 Contact Detail 3 — Fax: 1234567

Yes
No

3 PRODUCT INFORMATION — PROCEED

3.1 Product Category: Drug,Generic

Brand Name A
3.2.1 Generic Name: Generic Name A
3.2.2 EDL? No
3.2.3 No. of Samples: 2
3.3.0 Dosage Strength: Dosage Strength
3.3.1 Dosage Form: Dosage Form
3.3.2 Pharma Category Category:
3.4.0 Packaging: Packaging
3.4.1 Presentation: Presentation
3.4.2 Storage Condition: Storage
3.4.3 Shelf-life: Shelf-life
3.4.4 Sugg. Retail Price: SRP

3.6 Is the product a Principal Drug Product (PCPR) or an Identical Drug Product (CIDP)? No
4564365
31-Jan-15

4 SUPPORTING INFORMATION — PROCEED — Add

PROCEED
Repacker
Packer
Importer
Wholesaler
Exporter

PROCEED
Local Finished
Raw Material
Imported Finished

PROCEED
Product A
Product B
Product C
Product D
Product E
Product F
Product G
Product H
Product I
Product J
Product K
Product L
Product M
Product N
Product O
Product P
Product Q
Product R
1

PROCEED
Medicinal Gas
Cephalosphorins
Dermatologicals
Household Remedies
Non-Penicillin
Penicillin
Stem Cell
Vaccine
Veterinary
Nothing Further

5 SOURCES & CLIENTS — PROCEED

1 — Add — Source

5.1.1 Type of Establishment:	Wholesaler
5.1.2 Name of Source	Client A
5.1.3 Office Address	Office of Client A
5.1.4 Local FDA License Number:	NA
5.1.5 Tax Identification Number:	123456789
5.1.6 Contact Detail 1 — Landline:	landline
5.1.7 Contact Detail 2 — Mobile:	mobile

2 — Add — Source

5.2.1 Type of Establishment:	Processor
5.2.2 Name of Source	Source A
5.2.3 Office Address	Office of Source A
5.2.4 Local FDA License Number:	11111111
5.2.5 Tax Identification Number:	1233456789
5.2.6 Contact Detail 1 — Mobile:	mobile
5.2.7 Contact Detail 2 — Mobile:	mobile

3 — Add — Source

5.3.1 Type of Establishment:	Wholesaler
5.3.2 Name of Source	Source B
5.3.3 Office Address	Office of Source B
5.3.4 Local FDA License Number:	NA
5.3.5 Tax Identification Number:	NA
5.3.6 Contact Detail 1 — Landline:	Landline
5.3.7 Contact Detail 2 — Mobile:	Mobile

4 — None

6 APPLICANT INFORMATION — PROCEED

The undersigned attest to have provided true and complete information in this form, and to provide complete requirements at the time of submission. The undersigned agree to strict compliance with the rules and regulations of the Food and Drug Administration (FDA), including Good Manufacturing Practice (GMP), Good Distribution and Storage Practice (GDSP), Good Pharmacy Practice (GPP), and/or Good Laboratory Practice (GLP). Further, the undersigned agree to grant authority to the FDA to verify the truthfulness of the information provided with this application.

6.1 APPROVING AUTHORITY

Latest photo of applicant
Signature
6.1.1.0 Family Name: **Family Name**
6.1.1.1 First Name(s): **First Name**
6.1.1.2 Middle Name: **Middle Name**
6.1.2 Designation: Authorized Representative
6.1.3 Tax ID Number: 111-111-111
6.1.4.0 Type of Gov't ID: Land Transportation Office (Driver's)
6.1.4.1 ID Number: 123-456-789
6.1.4.2 Date Expiry: 31-Dec-14

6.1.5 Mailing Address: Mailing Address
6.1.6.0 E-mail Address: emailaddress@establishment.com
6.1.6.1 Contact Detail 1 — Landline: landline
6.1.6.2 Contact Detail 2 — Mobile: mobile
6.1.6.3 Contact Detail 3 — Fax: fax

6.2 APPLICANT

Latest photo of applicant
Signature
6.2.2.0 Family Name: **Family 2**
6.2.2.1 First Name(s): **First 2**
6.2.2.2 Middle Name: **Middle 2**
6.2.2 Designation: Authorized Representative
6.2.3 Tax ID Number: 333-333-333
6.2.4.0 Type of Gov't ID: Social Security System
6.2.4.1 ID Number: 123-456-789
6.2.4.2 Date Expiry: 31-Dec-16

6.2.5 Mailing Address: Mailing Address 1
6.2.6.0 E-mail Address: emailaddress@establishment.com
6.2.6.1 Contact Detail 1 — Landline: landline
6.2.6.2 Contact Detail 2 — Mobile: mobile
6.2.6.3 Contact Detail 3 — Fax: fax

ANNEX II

This is the petition form for establishment licensing by the Food and Drug Administration of the Philippines.

PETITION

We categorically declare that all data and information submitted in connection with this application as well as other submissions in the future including amendments, are true, correct, and reflect the total information available.

I/we am/are duly authorized to affirm the following declaration on behalf of the Company: **Demonstration Establishment**

I. The said establishment shall be open for business hours under the supervision of a PRC registered professional (if applicable) or authorized personnel;

II. The pharmacist and other allied health professionals, upon and during employment in this establishment, is/are not and will not in any way be connected with any other FDA-regulated establishment (if applicable);

III. The approved and valid License to Operate shall be displayed in a conspicuous place of the establishment;

IV. To change the business name of the establishment and/or brand name of products in the event that there is a similar or same name registered with the Food and Drug Administration, or if the FDA rules later that it is misleading;

V. The attached electronic copy of files/documents/information of the LTO application are the exact duplicate of the hard copy and, any discrepancy, prejudicial contents or willful misrepresentation on any of the data therein shall be a ground for disapproval of application and/or the filing of legal action against the undersigned and/or the company;

VI. If applying for automatic renewal:

a. Have filed the application, and have paid the complete & appropriate renewal fee before expiry date;

B. That there are no changes or variations in the establishment since the last renewal of LTO specifically but not limited to change of location, change of ownership, change of business name, change of registered pharmacist, change in warehouse site, additional supplier and product lines, change in activity, change in key personnel;

VII. The products we manufacture, distribute and/or sell are registered or to be registered with FDA prior to distribution or sale, and that we assume primary responsibility and/or stewardship over the product in case of liability, adverse events, and/or other public health & safety issues;

VIII. The establishment whether for initial, renewal or automatic renewal, is still subject to inspection by FDA's authorized representatives at any reasonable time and undertake to respond and cooperate fully with the FDA with regard to any subsequent post-marketing activity;

IX. Non-compliance with the requirements and/or failure to give notice to the FDA of the change in business address, business name, ownership, or any other circumstances in relation to the approval of this application is a ground for revocation of the License to Operate;

X. Any violation of the above provisions and rules and regulations will automatically be subject to the SUSPENSION/ CANCELLATION/ REVOCATION of the License to Operate.

XI. I/We make this declaration in full knowledge and awareness of Republic Act No. 3720, as amended by Republic Act no. 9711, otherwise known as the Food and Drug Administration Act of 2009, other allied laws and their implementing rules and regulations.

WHEREFORE, the undersigned confirm the truth of our declaration and awareness of the foregoing duties and responsibilities among others, and prays that this application for License to Operate be granted after compliance with the Food and Drug Administration's requirements.

WAIVER

I HEREBY GRANT AUTHORITY TO THE FOOD AND DRUG ADMINISTRATION TO VERIFY THE AUTHENTICITY OF ALL THE DOCUMENTS SUBMITTED FROM BOTH GOVERNMENT AND PRIVATE RESOURCES.

ACKNOWLEDGEMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____ day of _____ 20_____ at _____

_____, Philippines, personally appeared the following :

Name and Signature	Identification Number	Expiry Date of ID	Place Issued
1) First Name Middle Name Family Name	Land Transportation Office (Driver's):123-456-789	31-Dec-14	_____
2) First 2 Middle 2 Family 2	Social Security System:123-456-789	31-Dec-16	_____

Known to me and to me known to be the same persons who execute the application form and this petition form, and they acknowledged to me that the same is their free and voluntary act and deed. WITNESS MY HAND AND SEAL on the date and place first above written.

Doc. No. : _____

Page No. : _____

Book No. : _____

Series of : _____

ANNEX III

This is the declaration form for non-pharmaceutical product registration or notification by the Food and Drug Administration of the Philippines.

DECLARATION

We assume primary responsibility and/or stewardship over the product in case of liability, adverse events, or other public health & safety issues arising from its use. We agree to have exerted at least minimal diligence in ensuring that intellectual property rights are observed. We further agree and bind ourselves that the label of the product shall at all times conform to the labeling regulations, and shall not be presented including any advertisement of the product in a manner that is false, deceptive, misleading, or contrary to public policy. Non-observance of any of the undertakings in this declaration is deemed a misrepresentation which is a ground for disapproval of this application or, if approved, the suspension or cancellation of the product registration/ notification.

Enclosed are the documents stated in the Checklist of Requirements for Registration of our product:

Brand Name A;

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future including amendments, are true and correct and reflect the total information available.

We certify that we have examined the following statements and we attest to their accuracy and truthfulness:

1. The attached electronic copy of files/documents/information of this application are the exact duplicate of the hard copy and, any deficiency, discrepancy, prejudicial contents or willful misrepresentation on any of the data therein shall be a ground for disapproval of application and/or the filing of legal action against the undersigned and/or the company;
2. The market authorization holder has a risk management protocol including a standard operating procedure for handling adverse event reports of its products, and if needed, a product recall.
3. All the documentation referred to or required in this application is available for review during an audit or an inspection.
4. Any change in formulation, labelling, technical specification, or any deviation on any information given in respect of this application will first have to be known to, cleared, and/or approved by the Food and Drug Administration.

WAIVER

I HEREBY GRANT AUTHORITY TO THE FOOD AND DRUG ADMINISTRATION TO VERIFY THROUGH BOTH GOVERNMENT AND PRIVATE RESOURCES THE AUTHENTICITY OF ALL THE INFORMATION AND DOCUMENTS SUBMITTED .

ACKNOWLEDGEMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____ day of _____ 20_____ at _____

_____, Philippines, personally appeared the following :

Name and Signature	Identification Number	Expiry Date of ID	Place Issued
1) First Name Middle Name Family Name	Land Transportation Office (Driver's):123-456-789	31-Dec-14	_____
2) First 2 Middle 2 Family 2	Social Security System:123-456-789	31-Dec-16	_____

Known to me and to me known to be the same persons who execute the application form and this declaration form, and they acknowledged to me that the same is their free and voluntary act and deed. WITNESS MY HAND AND SEAL on the date and place first above written.

Doc. No. : _____

Page No. : _____

Book No. : _____

Series of : _____

ANNEX IV

This is the declaration form for pharmaceutical product registration by the Food and Drug Administration of the Philippines.

DECLARATION

We assume primary responsibility and/or stewardship over the product in case of liability, adverse events, or other public health & safety issues arising from its use. We agree to have exerted at least minimal diligence in ensuring that intellectual property rights are observed. We further agree and bind ourselves that the label of the product shall at all times conform to the labeling regulations, and shall not be presented including any advertisement of the product in a manner that is false, deceptive, misleading, or contrary to public morals/ public policy. Non-observance of any of the undertakings in this declaration is deemed a misrepresentation which is a ground for disapproval of this application or, if approved, the suspension or cancellation of the product registration.

Enclosed are the documents stated in the Checklist of Requirements for Registration and representative sample of our product.

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available. We certify that we have examined the following statements and we attest to their accuracy and truthfulness :

1. The current Good Manufacturing Practice Guidelines is applied in full in the manufacture of this product.
2. The formulation per dosage form is in agreement with the master formula and with the batch manufacturing record forms.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing records.
4. Product covered by this declaration will not undergo any change in formulation, dosage form, strength, therapeutic indication, manufacturer, manufacturing process, labelling or commercial presentation without prior approval of the Food and Drug Administration.
5. Each batch of all starting materials is tested or certified (in an accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and fully complied with those specifications cited in the claimed reference official monograph before it is released for manufacturing purposes.
6. All batches of active pharmaceutical ingredient/s (API) are obtained from the following sources:

Active Pharmaceutical Ingredient (API)	Name and Address of API Manufacturer	Name and Address of API Supplier
1) Active Pharmaceutical Ingredient;	1) API Manufacturer, Address Address Address;	1) API Supplier, Address Address Address;
2) Active Pharmaceutical Ingredient;	2) API Manufacturer, Address Address Address;	2) API Supplier, Address Address Address;
3) Active Pharmaceutical Ingredient;	3) API Manufacturer, Address Address Address;	3) API Supplier, Address Address Address;
4) Active Pharmaceutical Ingredient;	4) API Manufacturer, Address Address Address;	4) API Supplier, Address Address Address;
5) Active Pharmaceutical Ingredient;	5) API Manufacturer, Address Address Address;	5) API Supplier, Address Address Address;
6) Active Pharmaceutical Ingredient;	6) API Manufacturer, Address Address Address;	6) API Supplier, Address Address Address;
7) Active Pharmaceutical Ingredient;	7) API Manufacturer, Address Address Address;	7) API Supplier, Address Address Address;
8) Active Pharmaceutical Ingredient;	8) API Manufacturer, Address Address Address;	8) API Supplier, Address Address Address;
9) Active Pharmaceutical Ingredient;	9) API Manufacturer, Address Address Address;	9) API Supplier, Address Address Address;
10) Active Pharmaceutical Ingredient;	10) API Manufacturer, Address Address Address;	10) API Supplier, Address Address Address;
11) Active Pharmaceutical Ingredient;	11) API Manufacturer, Address Address Address;	11) API Supplier, Address Address Address;
12) Active Pharmaceutical Ingredient;	12) API Manufacturer, Address Address Address;	12) API Supplier, Address Address Address;

7. No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer listed above is available.
8. Each batch of the finished product is tested and certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and fully complied with the specifications cited in the claimed reference official monograph before it is released for sale.
9. The person releasing the product for sale is an authorized and/or qualified person.
10. The procedures for control of the finished product have been validated for this formulation. The assay method has been validated for accuracy, precision, specificity and linearity.
11. The market authorization holder has a standard operating procedure for handling adverse reaction reports, and implementation of recall of its products.
12. All the documentation referred to in this application is available for review during an audit or inspection.

WAIVER

I HEREBY GRANT AUTHORITY TO THE FOOD AND DRUG ADMINISTRATION TO VERIFY THROUGH BOTH GOVERNMENT AND PRIVATE RESOURCES THE AUTHENTICITY OF ALL THE INFORMATION AND DOCUMENTS SUBMITTED .

ACKNOWLEDGEMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____ day of _____ 20_____ at _____

_____, Philippines, personally appeared the following :

Name and Signature	Identification Number	Expiry Date of ID	Place Issued
1) First Name Middle Name Family Name	Land Transportation Office (Driver's):123-456-789	31-Dec-14	_____
2) First 2 Middle 2 Family 2	Social Security System:123-456-789	31-Dec-16	_____

Known to me and to me known to be the same persons who execute the application form and this declaration form, and they acknowledged to me that the same is their free and voluntary act and deed. WITNESS MY HAND AND SEAL on the date and place first above written.

Doc. No. : _____

Page No. : _____

Book No. : _____

Series of : _____