



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

AUG 13 2013

ADMINISTRATIVE ORDER

No. 2013 - 0022

SUBJECT: Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers

I. RATIONALE

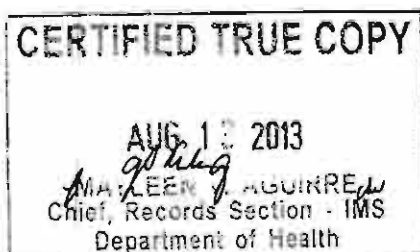
Whereas, it is the policy of the State as embodied in Article II, Section 15 of the 1987 Constitution to protect and promote the right to health of the people and instill health consciousness.

Pursuant to Republic Act 9711, it is the declared policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms, and initiatives that are aimed, directed and designed to protect and promote the right to health of the Filipino people.

And pursuant to Republic Act No. 7394, also known as "The Consumer Act of the Philippines", it is the policy of the State to protect the interest of the consumer, promote his general welfare and to establish standards of conduct for business and industry. Towards this end, the State shall implement measures to achieve for the protection against hazards to health and safety and protection against deceptive, unfair and unconscionable sales acts and practices.

Administrative Order 43 series of 1999 was created to institute and uphold the cGMP in the Philippines. As stated in Section 2, Drugs shall be manufactured using methods, facilities and control procedures adequate to preserve their identity, strength, quality and purity. Manufacturers must establish and maintain quality systems to assure that drug products are manufactured, held, and distributed in accordance with the cGMP and with the product application or license commitments.

Drug importers shall be responsible in ensuring that the products brought to the Philippines are manufactured in accordance with cGMP.



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Pursuant to Administrative Order 56 s. 1989, if an establishment imports raw materials, active ingredients and/or finished products for use in the manufacture of drug products, the establishment must submit a (1) certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and (2) evidence that the manufacturer meets FDA standards for local manufacturers.

An importer applying for registration or listing of drugs manufactured must provide an acceptable form of evidence to show that the drug is manufactured at an acceptable standard referred to as GMP Clearance of Foreign Drug Manufacturers. FDA Philippines shall inspect facilities to confirm manufacturers' compliance to cGMP. If inspection of the foreign manufacturer by FDA is necessary, the cost of inspection shall be borne by the applicant establishment.

This Order is issued under the authority conferred upon the Secretary of Health by virtue of section 26(a) of RA 3720 as amended.

II. OBJECTIVE

This Order aims to create and implement systems of evaluating, monitoring and assuring GMP compliance of foreign drug manufacturers who sell or offer for sale their drug products to the Philippines through submitted documentary evidences and GMP inspection, as appropriate.

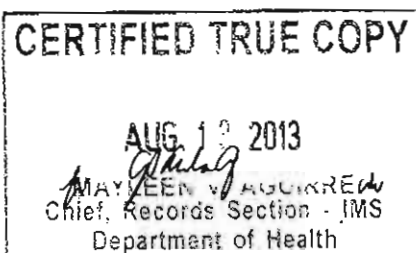
III. SCOPE OF APPLICATION

This Order shall apply to drug importers and foreign drug manufacturers.

IV. DEFINITION OF TERMS

For the purpose of this order, the following terms shall mean:

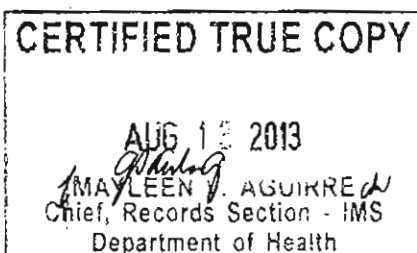
- a) "Drug Establishment" refers to drug manufacturers/ repackers, drug importers, drug distributors, drug wholesalers or drug exporters and entities belonging to definition of establishment, as per RA 9711 and its implementing rules and regulations.
- b) "Drug Manufacturer" means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage sale or distribution: Provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.



- c) "Establishment" means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.
- d) "GMP Evidence Dossier" refers to the documents used for the purpose of evaluating the GMP compliance of the foreign drug manufacturer such as, but not limited to, the Site Information/ Master File, GMP Inspection report, GMP Certificates, Validation Records and other documents.

V. GENERAL GUIDELINES

1. The Food and Drug Administration (FDA) shall create guidelines on the submission, review, monitoring and archiving of GMP evidences of foreign drug manufacturers.
2. Drug Importers must obtain GMP Clearance for the foreign drug manufacturer(s) before the health products are registered.
3. The drug importer shall provide evidence, on a periodic basis, that the product has been manufactured with the acceptable GMP standards.
4. The drug importer shall inform FDA Philippines on any changes with the foreign drug manufacturer that may have a direct or indirect impact on the quality and safety of the product or material introduced in the Philippine market.
5. The FDA may request additional documents for the assessment of the GMP Clearance application. Such request shall be put into writing and copy furnished the drug importer.
6. The FDA reserves the right to conduct an inspection of any foreign drug manufacturer, irrespective of the documentary GMP evidence submitted to the FDA, even if there is a current GMP Clearance.
7. The FDA may refuse the issuance of and suspend or cancel the GMP Clearance where evidence exist that the manufacturer does not meet the acceptable evidence of the standard of manufacture. The FDA shall inform the drug importer in writing on the non-approval, suspension or cancellation of the foreign manufacturer GMP clearance.
8. The FDA shall create and maintain a records and database of the submitted documentations, reports and correspondences.

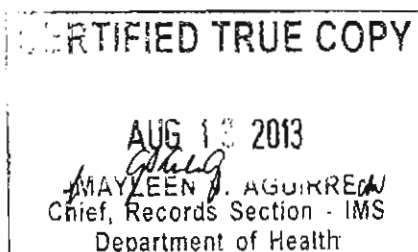


VI. SPECIFIC GUIDELINES

1. Authority to Evaluate and Monitor the GMP Evidence of Foreign Drug Manufacturers.

The FDA shall authorize the appropriate section, division or office, in charge of GMP, to re-evaluate, monitor GMP compliances of foreign drug manufacturers who sell or offer for sale their products in the Philippines.

2. The application for the foreign drug manufacturers clearance shall be as follows:
 - 2.1. The drug importer from the Philippines or the authorized representative shall be guided using the Notes on Application Form to Request for GMP Evidence Evaluation (Annex A) and apply using the GMP Evidence Evaluation Form (Annex B) for each manufacturing site and attach relevant evidence of the manufacturing standard, and forward it to the FDA for evaluation.
 - 2.2. The drug importer shall pay an evaluation fee for the submitted forms. The evaluation fee is non-transferable.
3. The GMP Evidence Evaluation Form and documents shall be assessed in accordance with the General Requirements for GMP Evidence Evaluation and other relevant rules and regulations of the FDA.
4. If approved, a GMP clearance letter will be issued bearing the following information:
 - 4.1 The name of the manufacturer
 - 4.2 The complete address of the manufacturing site
 - 4.3 The date of issue and/or expiry of the document
 - 4.4 The approved medicinal product(s) or approved type of medicinal products and dosage form(s)
 - 4.5 The approved steps of manufacture at the site
5. If denied, a denial letter from the FDA will be issued with the reason for such denial. New GMP evidence shall be submitted via filing of a new application.
6. Where no satisfactory documentary evidence of compliance can be provided, the Philippine drug importer shall accomplish the Application Form for Foreign Drug Manufacturer GMP Inspection (Annex D) and pay the necessary fees.
7. The application should be filed by an authorized representative.

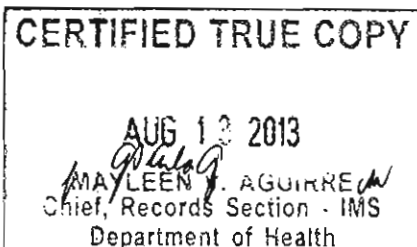


8. The importer shall submit:
 - a. GMP Evidence Dossier (Annex C) together with the completed application form.
 - b. Affidavit of undertaking (Annex E) that both the importer and manufacturer is agreeable to the on-site inspection.
9. The drug importer shall pay for the cost consisting of appropriate relevant inspection fee, travel and accommodation. Further, it is incumbent that the arrangement for the travel and accommodation be accomplished by them. The drug importer is also required to provide and shoulder the cost for a translator to be available, whenever necessary.
10. The appropriate fees for the Foreign GMP inspection can be paid upon the receipt of the notification from FDA or not later than 3 months from the scheduled inspection date.

VII. DOCUMENTARY REQUIREMENTS

A. Quality of documentation

- A.1 Original certificates shall be submitted.
- A.2 Where an original may not be obtained, a photocopy may be submitted provided all information on the copy must be clearly legible. Copies must be authenticated by the regulatory agency of the country of origin and/or a territorial Philippine consulate office.
- A.3 Copies of documents from Food and Drug Administration Philippines need not be notarized.
- A.4 Faxed, photocopied, scanned or emailed copies are not acceptable except for A.3.
- A.5 All certificates and other supporting documents must be in English.
- A.6 Bilingual certificates are acceptable provided one of the languages is English.
- A.7 If the document has been translated, a statement attesting the accuracy of translation from the translator is required. The FDA may require verification of the translated documents.
- A.8 The drug importer shall provide the following documents (as described in 2) issued by the relevant authority. The submitted documents shall bear the following information:
 - A.8.1 The name of the manufacturer
 - A.8.2 The specific address including the building number, floor, street address of the manufacturing site. (P.O. Box is not acceptable)
 - A.8.3 The date of issue and/or expiry of the document
 - A.8.4 The approved medicinal product(s) or approved type of medicinal products, dosage form(s)



- A.8.5 The approved steps of manufacture at the site if applicable.
- A.8.6 Date of last inspection
- A.8.7 The standard of manufacture with which the product complies.

A.9 Incomplete information shall not be accepted nor evaluated.

B. Acceptable evidence of the standard of manufacture

B.1 Where possible, documentation should generally be from a government authority that is recognized by FDA Philippines. The standard of GMP inspections from the relevant regulatory authorities of the following countries shall be acceptable:

- B.1.1 PIC/S Members countries
- B.1.2 Others countries
 - B.1.2.1 Japan Ministry of Health, Labour and Welfare

B.2 The acceptable GMP evidence issued by a competent authority listed may be in the form of:

- B.2.1 GMP Certificate (Certificate of GMP Compliance), or
- B.2.2 WHO Certificate of a Pharmaceutical Product; or
- B.2.3 Manufacturer's License or Manufacturing Authorization incorporating the specific medicinal product(s)/dosage form(s).

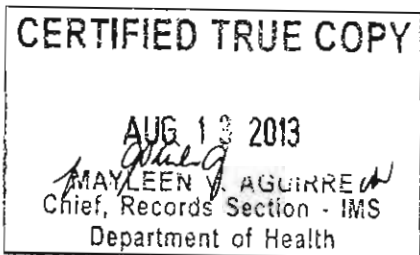
B.3 The following documentation shall not be accepted as primary evidence of GMP compliance although they may be useful supporting documentation:

- B.3.1 Copy of annual product registration certificate from US FDA
- B.3.2 Annual Registration of Drug Establishment Certificate from US FDA
- B.3.3 FDA Form 482 (Official FDA Notice of Inspection) and 483 (Official FDA Inspectional Observation Sheet)
- B.3.4 Letter from FDA stating that no form 483 was issued
- B.3.5 Other quality system certificate (e.g. ISO Certificate)

C. Validity of documents

C.1 The establishment shall provide new GMP evidence before the expiry date of the submitted documentary evidence of GMP conformance. Expired certificates/documents shall not be accepted.

C.2 GMP Certificates and inspection reports shall only be valid for three years after the date of the last inspection or until the expiry date shown on the certificate (whichever is earlier). If a certificate states that it is valid for more than three years after the date of inspection, it will only be accepted for a maximum of three years after the last inspection date. If a certificate has an expiry date less than three years after the inspection date, it will only be accepted until the stated expiry date.



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- C.3 There must be no qualifying statement on the GMP evidence that renders it invalid (e.g. a statement that 'the certificate is issued for the GMP and must not be used for any other purpose').
- C.4 The new GMP evidence shall be submitted via filing a new application.


This Order shall be periodically reviewed by the FDA. The establishments shall be given a 1-year transition period to comply with the said requirement starting from the effectivity date of this Order.

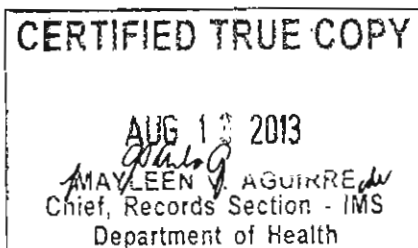
VIII. REPEALING CLAUSE

Provisions of previous issuances which are contrary to those reflected hereon are modified, and /or repealed accordingly.

IX. EFFECTIVITY

This Order shall take effect after fifteen (15) days following its publication in a newspaper of national circulation and upon submission to the University of the Philippines Law Center.


ENRIQUE T. ONA, MD
Secretary of Health



**NOTES ON APPLICATION FORM
TO REQUEST FOR GMP EVIDENCE EVALUATION**

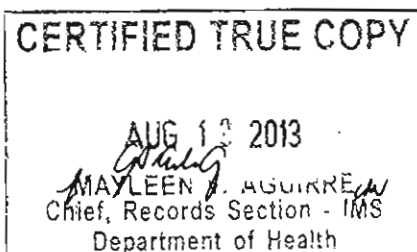
You will need the following information to fill in the form:

- a) FDA License to Operate document for locally registered company
- b) Valid documentary evidence of GMP conformance. The document should be translated into English if they are in other foreign language. If valid period is not stated on the Documentary Evidence of GMP conformance submitted, the evidence should not be older than one year at time of submission
- c) Details of overseas manufacturing site

1. This application form is for requesting the GMP evidence evaluation. The completed application form must be submitted together with the GMP evidence to the Food and Drug Administration Philippines - Regulation Division II.
2. The application should be made by a Philippine registered firm/company who should authorize a responsible person to request for GMP evidence evaluation.
3. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable. Incomplete information may cause unnecessary delay in processing the application.
4. If the space provided in the application form is insufficient, a separate sheet (A4 size) may be used. However, proper annex numbers should be made at the top right hand corner of such extension sheets.
5. All annexes should be listed in the "List of Annexes" provided, with the enclosure numbers corresponding to those in the columns of the application form.
6. The complete application form and GMP evidence must be sent to:

Regulation Division II
Food and Drug Administration Philippines
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

7. A service charge shall be payable for the GMP evidence evaluation upfront upon submission. Payment may be made in cheque (made payable to Food and Drugs Administration).





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Application No.
Registration Code

REQUEST FOR GMP EVIDENCE EVALUATION FORM

**Delete where applicable*

!Tick where applicable

[A] APPLICANT INFORMATION

A1. Name of company:

.....

(IN BLOCK LETTERS)

.....

Address:

.....

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.....

.....

Telephone No.:

.....

Fax No.:

.....

Company Registration No.:

.....

(Enclose photocopy of certificate)

A2. Person authorised to submit the application on behalf of the company

Name (*Mr/Ms/Mrs/Mdm/Dr):

.....

.....

(IN BLOCK LETTERS)

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Department of Health

*PRC No./Passport No./TIN No./Driver's License No.:

.....
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Designation:

.....

Residential address:

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.....

Telephone No.:

.....

Fax No.:

.....

Mobile Phone No.:

.....

Official E-Mail Address:

.....
.....

Preferred contact mode: Email / Fax *

(Please ensure that the relevant details above is entered for your preferred contact mode)

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MAYLEEN V. AGUIRRE
Chief, Records Section - IMS
Department of Health

[B] FOREIGN MANUFACTURER INFORMATION

B1. Name of Company:

.....

(IN BLOCK LETTERS)

.....

Company Address:

.....

.....

.....

.....

.....

.....

Telephone No.:

Fax No.:

B2. Manufacturing Site (If there is more than one manufacturing site, please specify all the sites, and provide all the relevant details as required below in a separate sheet.):

Address:

.....

.....

.....

.....

Telephone No.:

Fax No.:

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Mayleen W. Aguirre

MAYLEEN W. AGUIRRE
Chief, Records Section - IMS
Department of Health

[C] PHARMACEUTICAL DOSAGE FORM OF PRODUCTS MANUFACTURED / ASSEMBLED

Product Type	Manufacture	Primary Assembly	Secondary Assembly
Injection			
Admixtures for intravenous infusion			
Reconstituted cytotoxic preparations			
Total parenteral nutrition preparations			
Implants			
Sterile powder for injection			
Sterile non injectables liquid preparation			
Liquid preparations for inhalation			
Sterile semi-solid preparations			
Sterile powder for irrigations			
Sterile powder for topical application			
Intraocular drug delivery systems			
Sterile strips			
Oral liquid preparations			
Tablets for oral administration			
Soft Capsules			
Hard Capsules			
Pills			
Powders and granules for oral liquid preparations			
Oral powder and granules			
Pastille			
External liquid preparations			
Ear drops			
Nasal solution			
Foams			
Hemodialysis solution			
Non-sterile semi-solid preparations			
Non sterile powders for topical applications			
Powder for hemodialysis			
Powder Preparations for inhalation			
Suppositories			
Pessaries			
Medicated soap bars			
Transdermal patches			
Medicated gums			
Tablet for external administration			
Beads			
Solution for contact lens			
Dry powder inhalers			
Medicinal gases			
Others (please specify):			

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MAYRE *[Signature]* JUIRRE de
 Chief, Records Section - IMS

[D] GMP EVIDENCE

D1. Type of GMP evidence:

- GMP Certificate (Certificate of GMP Compliance)
- WHO Certificate of a Pharmaceutical Product
- Manufacturer's License or Manufacturing Authorization, incorporating the specific medicinal product(s)/dosage form(s)

D2. GMP evidence issued by:

Authority/Regulatory Agencies

Country

D3. Certificate/License reference no.:

D4. Validity of certificate/license:

[E] APPLICANT DECLARATION

1. I am hereby authorized by the company to make this application.
2. I undertake to pay all service charges related to the GMP evidence evaluation. I understand that service charges are payable upfront to Food and Drug Administration (FDA) Philippines and are non-refundable.
3. I undertake to ensure that the medicinal products are manufactured in accordance with Administrative Order 43 s. 1989, PIC'S Guide to Good Manufacturing Practice for Medicinal Products or equivalent.
4. I declare that the particulars given in this application are true and that the documents enclosed are authentic or true copies and undertake to notify the licensing authority within one week of any change in the particulars submitted in this application.

Signature :

Name :

Company stamp :

Date :

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MAYLEEN ROSARIO
Chief, Records Section - IMS
Department of Health

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Application No. :

Date received :

GMP evidence received : Yes No (if no, please reject the application)

Payment for GMP evidence evaluation received : Cheque Cash

Name of Bank and Branch:

Bank's Address:
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Cheque No:

Amount payable: Php _____

Name and signature of FDA officer receiving the application :
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.....

Remarks : To be routed to GMP Clearance Unit – Regulation Division II for Assessment ANNEX C.

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Annex C

GMP EVIDENCE DOSSIER

Documents Required	Manufacturing Steps					
	Full Manufacture	Bulk Manufacture	QC Testing	Packaging / Labeling	Release for supply	Sterilization
An original or notarized copy of a GMP certificate	✓	✓	✓	✓	✓	✓
A copy of the last inspection report and the manufacturer's response to any deficiencies noted	✓	✓	✓	✓	✓	✓
A copy of the GMP contract between the manufacturer and the Importer, including a list of the specific products for supply in the Philippines.	✓	✓	✓	✓	✓	✓
A copy of the Site Master File or equivalent	✓	✓		✓		
A copy of the Validation Master Plan (covering process, media fill (if relevant), cleaning, computerized systems, etc as applicable and including a Risk Assessment used to determine the scope and extent of validation)	✓	✓		✓		✓
Rationale for test method validation, procedure for method transfer etc.	✓	✓	✓			
Copies of the procedures for handling deviations and out of specification test results	✓	✓	✓	✓	✓	✓

Note: A ✓ means that the document is required

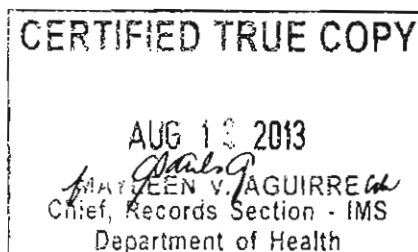
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 MAYLEEN AGUIRRE
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Application Form for Foreign Manufacturer GMP Inspection

- This form should be completed by the drug importer for each Foreign Drug Manufacturer.
- Incomplete forms may be returned to the applicant. Please type or print in black pen.
- Any alterations must be initialed and dated.
- The completed form should be sent to:

Postal: The Director
Food and Drug Administration
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City, Philippines



SECTION A

TO BE COMPLETED BY THE PHILIPPINE DRUG IMPORTER

SPONSOR NAME:	
SPONSOR ADDRESS:	
CONTACT NAME:.....
TELEPHONE:	FAX:
E-MAIL ADDRESS:

Note: The sponsors must pay the cost of the inspection (based on the current fees and charges) before the FDA GMP inspector leaves the Philippines, and the manufacturer must agree to the inspection. Otherwise, the inspection will not proceed.

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SECTION B

TO BE COMPLETED BY OR ON BEHALF OF THE FOREIGN MANUFACTURER

Manufacturing is defined as engaging in any operation involved in the production of drugs including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing, and labeling with the end in view of its storage, sale or distribution. This also includes assembling (device), storage, sterilizing, testing or release for supply of the goods or of any component or ingredient.

SPONSOR NAME:
SPONSOR ADDRESS:
CONTACT NAME: TELEPHONE: FAX: E-MAIL ADDRESS:
MANUFACTURER'S NAME:

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SECTION B-1

PRODUCT DETAILS –Specify type of product to be audited, eg tablet, herbal tablet, capsules, cream, heroral extracts, condoms, gloves etc	Specify the steps in manufacture that are conducted at this site, eg all steps in manufacture, packaging, release, manufacture of dosage form etc	Sterile Yes/no
1.	
2.	
3.	
4.	
5.	
6.	
7.	

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SECTION B-2

TO BE COMPLETED BY OR ON BEHALF OF THE FOREIGN MANUFACTURER
KEY PERSONNEL INFORMATION

1. Person in charge of production *and/*or assembly.

Production:

Name:

(IN BLOCK LETTERS)

*National Identification Number/Passport No.:

Designation: Directly reporting to:

(Position)

No. of years of relevant experience:

Assembly:

Name:

(IN BLOCK LETTERS)

*National Identification Number/Passport No.:

Designation: Directly reporting to:

(Position)

No. of years of relevant experience:

2. Person in charge of quality control *and/*or quality assurance.

Quality Control:

Name:

(IN BLOCK LETTERS)

*National Identification No./Passport No.:

Designation: Directly reporting to:

(Position)

No. of years of relevant experience:

Quality assurance:

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Name:

(IN BLOCK LETTERS)

*National Identification No./Passport No.:

Designation: Directly reporting to:

(Position)

No. of years of relevant experience:

3. Person who authorizes the release of products

Name:

(IN BLOCK LETTERS)

*National Identification No./Passport No:

Designation: Directly reporting to:

(Position)

No. of years of relevant experience:

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SECTION B-3

CONTRACT MANUFACTURER/ASSEMBLER INFORMATION

Contract manufacturer

Contract Assembler

The contractors refer to those engaged by the Foreign manufacturer. If there is more than one contractor, please specify all the contractors and provide all the relevant details as required below

1. Name of Company:

.....

(IN BLOCK LETTERS)

Company address:

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Telephone No.:

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Fax No.:

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Official e-mail address:

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2. *Manufacturing/ Assembling Site

Address:

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Tel No.:

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Fax No.:

.....
Official e-mail address:

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3. Scope of *Manufacturing / Assembling Activities (please specify):
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CONTRACT TESTING LABORATORY INFORMATION

Please state NIL if your company does not engage the services of any contract testing laboratories.

If there is more than one contract testing laboratory, please specify all the contract testing laboratories and provide all the relevant details as required below.

1. Name of testing laboratory:

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(IN BLOCK LETTERS)

Address:
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Chief, Records Section - IMS
Department of Health

Telephone No:

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Fax No:

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Official E-mail Address:

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2. Types of analytical tests performed:

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3. Is the contract testing laboratories accredited to ISO/IEC 17025 or other quality system standards? If so, please specify the standard and the scope of accreditation. Please attach the certificate of accreditation.


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PRODUCT DETAILS –Specify type of product to be inspected	Specify the steps in manufacture that are sub-contracted at this site	Sterile Yes/No
1.	
2.	
3.	
4.	
5.	
6.	
7.	

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SECTION C

Additional Information

INITIAL INSPECTION-Request for inspection

In order to schedule a GMP inspection by the FDA, the applicant should indicate an approximate date from which they will be ready. If this date changes after the application is submitted, the FDA GMP Inspectors should be notified as soon as possible.

Approximate date when ready for GMP inspection/...../.....

The actual date of the inspection will be advised to the company by the inspector assigned to undertake the inspection.

Site Master File/Quality Manual

Part of the reporting aspects of the inspection can be addressed by receiving information on related company details, e.g. details of the company's facilities, personnel structure and operating procedures including manufacturing activities, **prior to inspection.**

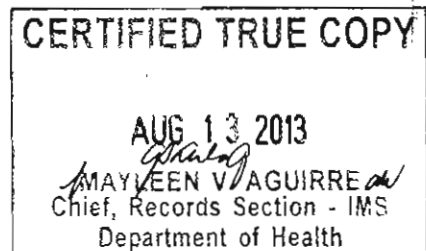
In the past, it was normal for the inspectors to spend some time, while on site, gathering this information. To reduce inspection time, and obvious expense to the inspectee, it is expected that this information should be prepared, in the form of a '**Site Master File**' for a **medical product manufacturer**, or a '**Quality Manual**' for a medical device manufacturer, by the inspectee for use by FDA GMP Inspectors.

It is requested that the Site Master File/ Quality Manual be enclosed, **prepared and forward these documents as soon as possible to the FDA Philippines.**

Enclosed - Yes No

For further information or queries regarding this application contact the following:

**Regulation Division II
Food and Drug Administration Philippines
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City, Philippines 1781
Telephone No.: 809-4390 loc 1281; 807-2843**



ANNEX F.

AFFIDAVIT OF UNDERTAKING

REPUBLIC OF THE PHILIPPINES

PROVINCE OF _____

MUNICIPALITY OF _____

I, _____ of legal age, single/married
residing at _____

_____ and authorized representative of
_____ a registered drug establishment of

The Food and Drug Administration Philippines located at

_____, with

LTO Number _____ and LTO validity _____, having been

Sworn in accordance with law, hereby declare:

1) that I have communicated with the foreign drug manufacturer with the business
name

_____ located at

_____ and the said foreign drug manufacturer allows the FDA Philippines to conduct inspection on
their site prior to issuance of GMP clearance.

2) that I am fully aware of the provisions that I shall arrange and pay the cost of
foreign drug manufacturer GMP audit including relevant audit fee travel and accommodation
costs within 15 days from the receipt of notice from FDA but not later than three (3) months
before the scheduled audit date.

3) that I shall pay services of translator during the conduct of inspection, as needed;

4) that I shall notify FDA in case of any change(s) in the circumstances of the
scheduled foreign drug manufacturer inspection not later than two weeks from the scheduled
inspection.

5) and that I fully understand that the FDA may disapprove the issuance of the GMP
clearance foreign drug manufacturer where evidence exist that the foreign drug manufacturer
does not meet the acceptable standards.

CERTIFIED TRUE COPY
AUG 13 2013
MAYLEEN A. AGUIRRE *du*
Chief, Records Section - IMS
Department of Health

I execute this Affidavit of Undertaking to confirm the truth of our declaration and my awareness of the foregoing duties and responsibilities among others.

IN WITNESS WHEREOF, I hereunto affix my signature this _____ day of _____, 20____, in the Municipality of _____, Province of _____, Philippines.

(Signature of Owner/ Authorized Representative)

Res. Cert. No. _____
Issued on _____
at _____

Subscribed and sworn to before me this _____ day of _____ at _____

Notary Public

Until December 31, _____

CERTIFIED TRUE COPY

AUG 13 2013
MAYKEEN V. AGUIRRE
MAYKEEN V. AGUIRRE
Chief, Records Section - IMS
Department of Health

ANNEX F.

**SCHEDULE OF FEES FOR GMP CLEARANCE AND FOREIGN DRUG
MANUFACTURER INSPECTION**

Fees	Rate
GMP Clearance Fees	
Application of GMP evidence, per manufacturer per site, per importer	Php 5,000 per application
Reinstatement of expired GMP Approval	Php 2,000
Desktop Inspection (in lieu of the Foreign GMP inspection)	Php 5,000 per application per site
Reissuance of the GMP clearance	Php 1,000
GMP Foreign Inspection Fees	
Application Fee for Foreign Drug Manufacturer Inspection	Php 3,000 per application per site
Inspector's fee	
2.1 ASEAN Countries	US\$ 3,500 + Current United Nation Development Program – Daily Subsistence Allowance (UNDP-DSA) Rates on the audited site/ region
2.2 Asia Pacific Countries	US\$ 7,000 + Current United Nation Development Program – Daily Subsistence Allowance (UNDP-DSA) Rates on the audited site/ region
2.3 All other countries outside of Asia Pacific	US\$ 10,500 + Current United Nation Development Program – Daily Subsistence Allowance (UNDP-DSA) Rates on the audited site/ region
	(Exclusive of cost of travel, accommodation and other incurred costs)

CERTIFIED TRUE COPY

AUG 13 2013

MAYLEN V. AGUIRRE
MAYLEN V. AGUIRRE
Chief, Records Section - IMS
Department of Health