CHECKLIST OF REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS
(For Human Use)

REQUIREMENTS	Type of Application	
	Initial	Renewal
1. Notarized Letter of Application as per BC # 1 s. 2002		
a) Annex A – including the following statements (per **A.O. 1 s. 2005**):	✓	
14) ***should the IPO or court of law of competent jurisdiction decide, with finality, that the applicant has no intellectual property right involving, or attached to, the pharmaceutical product, then any CPR issued to the product in question shall be deemed automatically cancelled and/or revoked; and***		
15) ***he acknowledges and agrees to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the registration of the pharmaceutical product concerned***		
Incorporate Additional Statement to Annex A (per A.O. 2005-0016) effective 05 August 2005:		
16) ***We shall change the brand name so submitted should the proper authority decides with finality that he/she/it has no right to appropriate and utilize said brand name; and***	✓	
17) ***We shall acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with BFAD.***	✓	
b) Annex B		✓
2. Form No. 8	✓	✓
3. Copy of Disapproval Letter indicating the old Routing Slip Number (where applicable))		
4. Copy of valid agreement between the manufacturer & Trader/distributor/importer/exporter	✓	
5. a) Copy of Latest Certificate of Product Registration		✓
b) For A. O. No. 54 s. 1998 (Change of Manufacturers of Drug Products in compliance with the CGMP Requirements) - Valid **original** Certificate of Product Registration (where applicable)		
6. Copy of valid LTO of the manufacturer/trader/importer/distributor reflecting the corresponding source(s)	✓	✓
a) License to Handle Controlled Substances issued by the Dangerous Drugs Board (Additional requirement for prohibited/regulated drugs)		
7. Unit Dose and Batch Formulation – in metric system	✓	✓
8. Technical Specifications of ALL RAW MATERIALS	✓	
9. Certificate of Analysis of Active Raw Material(s)		
a) From the manufacturer (supplier) of the active raw material	✓	
b) From the manufacturer of the Finished Product	✓	
10. Technical Specifications of the FINISHED PRODUCT	✓	✓
11. Certificate of Analysis of the FINISHED PRODUCT (from the same batch or lot of the representative sample submitted)	✓	✓
12. Master Manufacturing Procedure, Production Equipment, Sampling and In-Process Controls, and Master Packaging Procedure	✓	
13. Assay and other test procedures including Assay with Data Analysis e.g. chromatograms, if applicable [For NON-OFFICIAL FORMULATION, **assay validation report(s) for test procedure(s)**]	✓	✓
14. Stability Studies		
NATIONAL GUIDELINES:		
a) Accelerated – 1 batch at 3 elevated temperatures (40°C, 50°C, 60°C) ***OR***	✓	
b) Long-Term – 3 batches (30°C/70%±5%RH)	✓	✓
ASEAN HARMONIZED GUIDELINES:		
a) Accelerated – 2 batches (3 batches for New Drug) at 40°C/75% RH ***AND***	✓	
b) Long Term Stability Studies – 2 batches (3 Batches for New Drug) (30°C/75% RH) as adopted in the 8th ACCSQ PPWG Meeting	✓	✓
c) In-Use Stability Studies (Additional requirements for Powder for Suspension)	✓	
c.1) 1 batch at 30°C (7 days) and 2 to 8°C (14 days)		✓
c.2) 3 batches at 30°C (7 days) and 2 to 8°C (14 days)		
15. Representative Sample in market or commercial presentation **(at least 1 year before expiry)**	✓	✓
16. Labelling Materials		
a) Facsimile labels **with actual color text** (3 copies)	✓	
b) **Actual**/Commercial labeling materials (3 copies)		✓
17. Bioavailability/Bioequivalence Studies (where applicable)	✓	✓ (For Rifampicin products)

18. Dissolution Profile for Drugs in List B Prime (12 units Test Product versus Reference including computation of Similarity Factor (f2) as per B.C. No. 13-A s. 1999	✓	✓
19. For New Drug Applications a) Copy of ACB Approval on pre-clinical, clinical and Protocol for Monitored Release (MR) b) Copy of ACB Approval on the rationale of Fixed Dose Combination Product (if applicable) c) Copy of ACB Approval of Post-Marketing Surveillance (PMS) or Letter of Extension of MR Status (if applicable)	✓ ✓	 ✓
20. For Imported Products (an English translation shall accompany any document not written in English) ▪ ORIGINAL Certificate of Pharmaceutical Product (issued at least 1 year form the date the application for registration was filed) ▪ For Countries not issuing CPP, the following may be accepted: a) Certificate of Free Sale from the country of origin, duly authenticated by the territorial Philippine Consulate b) Government Certificate attesting the registration status of the manufacturer, duly authenticated by the territorial Philippine Consulate	✓	
21. For Products in Plastic Container a) General Information b) Studies done on the plastic to substantiate claim that the product is safe to use c) Test Procedures and Limits d) Empty plastic container and closure with corresponding proof of payment for laboratory analysis	✓	
22. Evidence of Registration fee/payment (Charge slip/official receipt)	✓	✓

Additional Requirement for New Drug Applications: Reference Standard

Revised: 07/08/05 ctc/psd

BUREAU OF FOOD AND DRUGS
FORM NO. 8

APPLICATION FOR REGISTRATION OF PHARMACEUTICAL PRODUCT

To be filled up by the applicant

A. **COMPANY APPLICANT**

Company Name:

Complete Address:

Contact Numbers:

Type of establishment

[ ] Manufacturer [ ] Trader [ ] Importer/Distributor/Wholesaler
[ ] importer in bulk & repacked locally
[ ] imported finished and packed locally
[ ] imported finished product

LTO Number:

Valid Until:

DATA ON [ ] MANUFACTURER [ ] REPACKER

Complete Name:

Complete Address:

B. **TYPE OF APPLICATION**

[ ] INITIAL REGISTRATION
[ ] Established Drug
[ ] New Drug (Monitored Release)
[ ] Fixed Dose Combination
[ ] RENEWAL REGISTRATION
[ ] MONITORED RELEASE EXTENSION
ACB Approved Extension [ ] 1 yr [ ] 2 yrs [ ] 3 yrs
BFAD Registration Number
Valid Until:

C **COMPLETE INFORMATION REGARDING THE PRODUCT**

1. Generic Name (s) :
2. Brand Name, if any:
3. Dosage Strength:
4. Dosage Form
5. Route of Administration
6. Pharmacologic Category
7. Classification
[ ] Rx (Prescription Drug) [ ] OTC (Over-the-Counter [ ] Restricted/Regulated
Essential Drug List (EDL)
[ ] Yes [ ] No
8. Claimed Shelf Life
9. Storage Condition
10. Primary packaging (Market/Commercial Presentation):
11. Suggested Retail Price (As per A.O. #48-C s. 1999) P / unit
12. Reference Monograph:
[ ] Official [ ] Non-Official

CHECKLIST OF REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS

(For VETERINARY Use)

REQUIREMENTS	Type of Application	
	Initial	Renewal
1. Notarized Letter of Application as per BC # 1 s. 2002 a) Annex A – including the following statements (A.O. 1 s. 2005): *a.1) should the IPO or court of law of competent jurisdiction decide, with finality, that the applicant has no intellectual property right involving, or attached to, the pharmaceutical product, then any CPR issued to the product in question shall be deemed automatically cancelled and/or revoked; and* *a.2) he acknowledges and agrees to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the registration of the pharmaceutical product concerned* b) Annex B	✓	✓
2. Form No. 8	✓	✓
3 Copy of Disapproval Letter indicating the old Routing Slip Number (where applicable)		
4. Copy of valid agreement between the manufacturer and trader/distributor/importer/exporter	✓	
5. Copy of Latest Certificate of Product Registration.		✓
6. Copy of valid LTO of the manufacturer/trader/importer/distributor reflecting the corresponding source(s) (issued by BFAD/BAI)	✓	✓
7. Unit Dose and Batch Formulation – in metric system	✓	✓
8. Technical Specifications of ALL RAW MATERIALS	✓	
9. Certificate of Analysis of Active Raw Material(s) a) From the manufacturer (supplier) of the active raw material b) From the manufacturer of the Finished Product	✓ ✓	
10. Technical Specifications of the FINISHED PRODUCT	✓	✓
11. Certificate of Analysis of the FINISHED PRODUCT (from the same batch or lot of the representative sample submitted)	✓	✓
12. Master Manufacturing Procedure, Production Equipment, Sampling and In-Process Controls, and Master Packaging Procedure	✓	
13. Assay and other test procedures including Assay with Data Analysis e.g. chromatograms, if applicable [For NON-OFFICAL FORMULATION, **assay validation report(s) for test procedure(s)**]	✓	✓
14. Stability Studies NATIONAL GUIDELINES: a) Accelerated – 1 batch at 3 elevated temperatures (40^0C, 50^0C, 60^0C) **OR** b) Long-Term – 3 batches (30^0C/70%±5%RH) ASEAN HARMONIZED GUIDELINES: a) Accelerated – 2 batches (3 batches for New Drug) at 40^0C/75%RH **AND** b) Long-Term Stability Studies – 2 batches (3 Batches for New Drug) (30^0C/75%RH) as adopted in the 8th ACCSQ PPWG Meeting c) In-Use Stability Studies (Additional requirements for Powder for Suspension) c.1) 1 batch at 30^0C or 2 to 8°C c.2) 3 batches at 30^0C or 2 to 8°C	✓ ✓ ✓ ✓ ✓	✓ ✓ ✓
15. Representative Sample in market or commercial presentation (**at least 1 year before expiry**)	✓	✓
16. Labelling Materials a) Facsimile labels **with actual color text** (3 copies) b) **Actual**/Commercial labeling materials (3 copies)	✓	✓
17. For New Drug Applications a) Submit pre-clinical studies, foreign and local clinical trials and protocol/s for Monitored Release For Fixed Dose Combination b) Submit Rationale of the combination	✓ ✓	
18. For Imported Products (an English translation shall accompany any document not written in English) ▪ ORIGINAL Certificate of Pharmaceutical Product (issued at least 1 year form the date the application for registration was filed) ▪ <u>For Countries not issuing CPP</u>, the following may be accepted: a) Certificate of Free Sale from the country of origin, duly authenticated by the territorial Philippine Consulate b) Government Certificate attesting the registration status of the manufacturer, duly authenticated by the territorial Philippine Consulate	✓	
19. For Products in Plastic Container	✓	

a) General Information b) Studies done on the plastic to substantiate claim that the product is safe to use c) Test Procedures and Limits d) Empty plastic container and closure with corresponding proof of payment for laboratory analysis		
20. Evidence of Registration fee/payment (charge slip/official receipt)	✓	✓

BUREAU OF FOOD AND DRUGS
FORM NO. 8

APPLICATION FOR REGISTRATION OF PHARMACEUTICAL PRODUCT

To be filled up by the applicant

A.	**COMPANY APPLICANT**
	Company Name:
	Complete Address:
	Contact Numbers:
	Type of establishment
	[ ] Manufacturer [ ] Trader [ ] Importer/Distributor/Wholesaler
	[ ] importer in bulk & repacked locally
	[ ] imported finished and packed locally
	[ ] imported finished product
	LTO Number:
	Valid Until:
	DATA ON [ ] MANUFACTURER [ ] REPACKER
	Complete Name:
	Complete Address:
B.	**TYPE OF APPLICATION**
	[ ] INITIAL REGISTRATION
	[ ] Established Drug
	[ ] New Drug (Monitored Release)
	[ ] Fixed Dose Combination
	[ ] RENEWAL REGISTRATION
	[ ] MONITORED RELEASE EXTENSION
	ACB Approved Extension [ ] 1 yr [ ] 2 yrs [ ] 3 yrs BFAD Registration Number
	Valid Until:
C	**COMPLETE INFORMATION REGARDING THE PRODUCT**
	1. Generic Name (s) :
	2. Brand Name, if any:
	3. Dosage Strength:
	4. Dosage Form
	5. Route of Administration
	6. Pharmacologic Category
	7. Classification [ ] Rx (Prescription Drug) [ ] OTC (Over-the-Counter [ ] Restricted/Regulated Essential Drug List (EDL) [ ] Yes [ ] No
	8. Claimed Shelf Life
	9. Storage Condition
	10. Primary packaging (Market/Commercial Presentation):
	11. Suggested Retail Price (As per A.O. #48-C s. 1999) P / unit
	12. Reference Monograph:
	[ ] Official [ ] Non-Official

CHECKLIST OF REQUIREMENTS FOR REGISTRATION OF

VACCINES/BIOLOGIC PRODUCTS

I. INITIAL APPLICATION

a. Imported as Finished Product and Locally Produced Product

- Letter of Application (Annex A as per B.C. 1 s. 2002 including A.O. 1 s. 2005-Afficavit of Undertaking)
- Form 8
- Copy of valid LTO of Manufacturer/Trader/Importer/Distributor
- Copy of valid agreement between manufacturer and trader/importer/distributor, when applicable
- Original Certificate of Pharmaceutical Product (CPP), issued at least 1 year from the date of application for registration was filed.

  For countries not issuing CPP, the following may be accepted:
  1. Latest GMP Certificate issued by the NRA of the exporting country, duly authenticated by the territorial Philippine Consulate
  2. Certificate of Free sale from the country of origin, duly authenticated by the territorial Philippine Consulate

- List of Countries where the vaccine is already licensed and the date of approval
- Information on the Product and Manufacturing/Production Process:
  - Person/s responsible for production and control of the product. (Name/s Position, Department, and sample of signature)
  - Information on the source of materials (e.g. microorganisms, cell/cell substrates), including their specifications and tests used to demonstrate compliance with the specifications.
  - Information on the methods of manufacture, including description of the seed lot and cell substrate systems used, together with in-process, bulk and final product specifications and the tests used to demonstrate compliance.
  - Documentation used in the manufacturing and control procedures, including SOPs and protocols containing details of production and quality control testing carried out in all stages and production. Information on the number system of the lots or batches, including individual component of the formulation.
  - Demonstration of lot-to-lot consistency of production on a minimum of 3 consecutive batches.
- Report on pre-clinical studies, if appropriate
- Report on Clinical Trials, as appropriate
  - New Biologic Product
    - Phase IV Clinical trial protocol, or BFAD Approval
    - Phase I, II, and Clinical Studies
      - Dose Response Studies
      - Protective Efficacy (natural and Artificial Challenge)
      - Relationship between Immune Response and Protection
      - Rate of fall of response and loss of Protection
      - Re-vaccination studies, where applicable
      - Studies in relevant sub-groups
      - Lot-to-lot consistency study (retrospective)
  - Established Biological Product
    - Phase IV Clinical Trial
  - Live
    - Transmission to Contact Studies
    - Vaccine Induced Disease Studies
    - Effect on large scale vaccination on the natural history of the disease

- Combination of Biologic Product
  - Clinical data on Efficacy
    - Clinical evidence of consistency of combination
    - Interaction Studies
  - Clinical data on Safety
    - Comparison on local reactions (Combination vs Separate)
    - Comparison on combination with worst of separate vaccines

- ♦ Stability Studies undertaken to justify the proposed validity period for the product under the indicated storage conditions.
- ♦ Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)
- ♦ System for the re-processing of the product in event of rejection of the lot or batch by the manufacturer's QA/QC.
- ♦ Three (3) product samples
- ♦ Three (30 attached labeling materials (primary, secondary, inserts)
- ♦ Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to BFAD
- ♦ Other information or special condition of the product in the country of origin, if any (e.g. lot releasing system)

b. Donated Vaccine/Biologic Products

- ♦ Letter of Application (Annex A as per BC 1 s. 2002 including A.O. 1 s. 2005 – Affidavit of Undertaking)
- ♦ Form 8
- ♦ If the product is not yet registered with BFAD, the same requirements shall be submitted as the imported finished product and locally produced product.
- ♦ If the product is already registered with BFAD, submit the following:
  - Inventory of the number of vials per lot or batch to be donated
  - Summary Lot or Batch Protocol with the Certificate of Lot/Batch Release from the NRA of the exporting country per batch or lot to be donated
  - Name of medical director responsible for monitoring AEFI and prepare appropriate report to be submitted to BFAD

II. RENEWAL APPLICATION

- ♦ Letter of Application (Annex B as per BC 1 s. 2002 - Affidavit of Undertaking need not be included)
- ♦ Form 8
- ♦ Original Certificate of Pharmaceutical Product (CPP), issued at least 1 year from the date the application for registration was filed.
  For countries not issuing CPP, the following may be accepted
  1. Latest GMP Certificate issued by the NRA of the exporting country, duly authenticated by the territorial Philippine Consulate
  2. Certificate of Free sale from the country of origin, duly authenticated by the territorial Philippine Consulate
- ♦ List of Countries where the vaccine is already licensed and the date of approval
- ♦ Adverse event following immunization report (Summary of Annual Reports) for established and new biologics
- ♦ Phase for Clinical Trial Report for New Biologic Products
- ♦ Certification that there were no changes during the 5-year period. If there were any, submit the summary changes made by the manufacturer for the 5-year period.
- ♦ Summary of Lot Protocol

CHECKLIST FOR REGISTRATION OF

MEDICAL DEVICES

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Notarized Letter of Application from Manufacturer/ Trader/ Distributor	✓	✓
2. Certificate of Brand Name Clearance (for branded products)	✓	
3. Valid License to Operate (LTO) of Manufacturer/Trader/Importer/Distributor/Wholesaler	✓	✓
4. Government Certificate of Clearance and Free Sale/Registration approval of the product from the country of origin issued by Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product	✓	
5. Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities and duly authenticated by the territorial Philippine Consulate and/or valid ISO Certification for Imported Product	✓	
6. Certificate of agreement between the manufacturer and trader/distributor/importer regarding the product involved.	✓	✓
7. Specific Use and Directions for Use.	✓	✓
8. Copy of latest Certificate of Product Registration (CPR)	✓	✓
9. List of Amount and technical specifications of all raw materials.	✓	✓
10. Brief description of the methods used, the facilities and control in the manufacture, processing and packaging of the product. For sterile products, include sterilization procedure.	✓	✓
11. Technical specification and physical description of the Finished product.	✓	✓
12. Stability studies of the product and physical description of the Finished Product.	✓	✓
13. Labeling materials to be used for the product: Immediate label, box label and package insert/brochures, if available.	✓	✓
14. Representative sample in the market or commercial presentation (at least one of each size)	✓	✓
15 Evidence of registration/payment (charge slip/official receipt)	✓	✓

APPLICATION FOR REGISTRATION OF MEDICAL DEVICES

For BFAD-PAICS use only
RSN |

PROF. LETICIA-BARBARA B. GUTIERREZ, M.S
Director
Bureau of Food and Drugs
Alabang, Muntinlupa City

ATTENTION: **Product Services Division**
Drug Section

Sir/Madam:

In Accordance with R.A. 3720 and other related issuances, we wish to apply for the ( ) initial ( ) renewal registration of our product.

Name of Medical Devices	
Brand Name (if any)	
Size/Product Code/Reference Number	
Primary Packaging (Market or Commercial Presentation)	
Registration Number	

Enclosed are the documents stated in the Checklist of Requirements for Registration and representative samples 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:

1. The Current Good Manufacturing Practice Guidelines for Medical Device 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 (if applicable)
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 the formulation, size, reference number, use, manufacturer, manufacturing process, labeling or commercial presentation without prior approval of this office.
5. Each batch of the finished product is tested and certified to be fully compliant with the specifications in the accompanying documentation.
6. The person releasing the product for sale is an authorized and/or qualified person.
7. The procedures for control of the finished product have been validated.
8. The market authorization holder has a standard operating procedure for handling any adverse event related to the use of the device.

9. The market authorization holder has a standard operating procedure for handling batch recalls.
10. All the documentation referred to in this application is available for review during a GMP inspection.
11. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize said brand name; and
12. We shall acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with BFAD.

COMPANY PHARMACIST
Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

OWNER/GENERAL MANAGER
Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

ACKNOWLEDGMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____
personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued
1.			
2.			

Known to me and to me know to be the same persons who execute the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.
WITNESS MAY HAND AND SEAL on the date and place first above written.

Doc. No. _____
Page No.. _____
Book No. _____
Series of _____

CHECKLIST FOR REGISTRATION OF DIAGNOSTIC PRODUCTS

REQUIREMENTS	Type of Application	
	Initial	Renewal
1. Notarized Letter of Application from Manufacturer/Trader/Distributor	✓	✓
2. Certificate of Brand Name Clearance (for branded products)	✓	
3. Valid License to Operate (LTO) of Manufacturer/Trader/ Importer/Distributor/Wholesaler	✓	✓
4. Government Certificate of Clearance and Free Sale/Registration approval of the Product from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product	✓	✓
5. Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities and duly authenticated by the territorial Philippine Consulate and/or valid ISO Certification for Imported Product	✓	
6. Certificate of agreement between the manufacturer and trader/distributor/importer regarding the product involved	✓	
7. Specific Use and Directions for Use	✓	
8. Copy of latest Certificate of Product Registration		✓
9. List of all raw materials used as components of the reagents/test kit	✓	
10. Technical specifications and physical description of the Finished product	✓	✓
11. Process-control/Test procedure and expected performance specification	✓	✓
12. Flowchart of the manufacturing procedure	✓	
13. Stability studies of the product to justify claimed shelf-life	✓	
14. Labeling materials to be used for the product: Immediate label, box label and package insert/brochures, if available	✓	✓
15. Representative sample in the market or commercial presentation * (15 Kits for pregnancy tests) (2 samples for drug screening test kits)	✓	✓
16. Evidence of registration fee/payment (charge slip/official receipt)	✓	✓

Note:

For HIV test kits and Hepatitis B & C Kits, refer to Annex A for additional requirements

For screening Drug Test Kits – refer to Annex B

*Samples of diagnostic kits other than pregnancy test kit shall be submitted only upon request/notification from the Reference Laboratory

Revised: 21/03/05 ctc/psd

ANNEX A

STANDARD AIDS COOPERATIVE CENTRAL LABORATORY (SACCL) REQUIREMENTS (for HIV, Hep B & C Test Kits)	Initial	Renewal
1 Letter of compliance to SACCL	✓	✓
2. Evaluation report for the past two years from any of the following (for HIV test systems only) ➢ WHO Collaborating Center HIV, Anwerp, Belgium ➢ WHO Collaborating Center for HIV, Fairfield, Australia ➢ US Food and Drug Administration ➢ Swedish Institute for Infectious Disease Control, Stockholm, Sweden ➢ National HIV Reference Laboratory, Central Public Health Laboratory, London, United Kingdom ➢ Paul Erlich Institute, Langen, Germany ➢ Independent investigators of National HIV and/or Serology Reference Laboratories ➢ Other WHO Collaboration Centers for HIV	✓	✓
3. Data on routine use of the kit in other countries, or valid Licensing Registration status in other countries (for HIV tests systems only)	✓	
4. Routine quality control tests on components of the kit and/or assembled kit prior to release.	✓	
5. Samples and other materials: *HIV Test Kits :* ➢ A minimum of 500 test equally divided into two (2) production lots. ➢ Expiration date should at least six (6) months from the date of submission. ➢ Must be transported in cold packing and received intact in the laboratory. ➢ EIA kits: ➢ Submission of HIV-1 positive seroconversion panel sera of not less than five (5) members containing 0.25-0.5 mL each. The panel details can be obtained from NRL/SACCL , or ➢ Submission of five (5) HIV-2 positive performance panel sera, 0.5mL each for HIV-1/HIV-2 combination kits ➢ Submission of one (1) "group O" positive performance panel sera, 0.5 mL for HIV containing antigens of HIV –1 "group O", or ➢ Submission of five (5) HIV p24 antigen positive performance panel sera, 0.5mL each, for HIV antibody test kits employing the detection of HIV antigenemia. ➢ For Rapid/Simple test kits: ➢ Submission of HIV-1 positive performance sera provided that the sensitivity is equal to or less than 50mg/ml. *Hepatitis B & C Kits:* ➢ A minimum of 500 test equally divided into two (2) production lots. ➢ Expiration date should be at least sie (6) months from the date of submission. ➢ Must be transported in cold packing and received intact in the laboratory. ➢ Submission of five (5) seroconversion panel sera, 1 mL each for Hepatitis B and Hepatitis C test kits. The panel details can be obtained from NRL/SACCL.	✓	✓
6. Payment of Php 25,000.00 performance evaluation fee to defray the cost of supplies and reagents used for the preparation of serum panels subject to change upon notice.	✓	✓
7. Product demonstration and performance of the test in a panel of samples to be provided by NRL/SACCL.	✓	

ANNEX B

EAST AVENUE MEDICAL CENTER (EAMC) REQUIREMENTS (DRUG TEST KITS)	**INITIAL**	**RENEWAL**
1. Letter of endorsement from BFAD.	✓	✓
2. Letter of compliance to NRL-EAMC. (In case of deficiency)	✓	✓
3. List of raw materials used as components of Drug Screening Test kits/Reagents.	✓	*
4. Test Procedures/In-process controls to conduct Drug Screening Test Kits.	✓	*
5. Physical description and technical specifications the drug screening products which includes: 5.1 Data on sensitivity and specificity tests to be conducted for: 5.1.1 Negative Specimens One hundred twenty (120) independent analyses using three different lot of different concentration from o to 50% below of cut-off. All test results must be negative for drug. 5.1.2 Positive Specimens One hundred twenty (120) independent analyses using three different lot of different concentration from o to cut-off to 150 cut-off. All test results must be negative for drug. 5.2 Other statistical indices that shall describe the performance characteristic of the test kits.	✓	*
6. Performance Comparison studies with GC/MS.	✓	*
7. Certificate of analysis of finished products	✓	✓
8. Not less than 150 samples for evaluation.	✓	✓
9. Evidence of registration fee/payment (charge slip/official receipt)	✓	✓

*** NRL will require if deemed necessary**

ASEAN COSMETIC TECHNICAL DOCUMENTS (ACTD) and ASEAN COSMETIC TECHNICAL REQUIREMENTS (ACTR)

ACTD

1. ASEAN Glossary
2. Organization of Dossier
   - 2.1. Part I: Table of Contents, Administrative Data, and Product Information
   - 2.2. Part II: Quality Document
   - 2.3. Part III: Nonclinical Document
   - 2.4. Part IV: Clinical Document

ACTR

1. ASEAN Guidelines on Stability Study of Drug Product
2. ASEAN Guidelines on Validation of Analytical Procedures
3. ASEAN Guidelines on Submission of Manufacturing Process Validation Data for Drug Registration
4. ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies
5. Guidelines on Nonclinical Documents
6. Guidelines on Clinical Documents

CHECKLIST for REGISTRATION of TRADITIONALLY-USED HERBAL PRODUCTS*

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Letter of Application as B.C. No. 01 s. 2002	√	√
2. Form No. 8 (Revised)	√	√
3. Copy of valid Certificate of Brand Name Clearance	√	
4. Copy of valid agreement between the manufacturer & trader/distributor/importer/exporter	√	
5. a) Copy of latest Certificate of Product Registration b) For A.O. No. 54 - valid original Certificate of Product Registration	√	√
6. Copy of valid LTO of the manufacturer/trader/importer/distributor, reflecting the product source(s)	√	√
7. Unit Dose and Batch Formulation	√	√
8. Technical Specifications of ALL Raw Materials	√	
9. Certificate of Analysis of Active Raw Material a) From the supplier of the active raw material (if applicable) b) From the manufacturer of the finished product c) Certification of Authenticity of Plant Specimen from the National Museum (Philippines) or any BFAD-recognized taxonomist In case of imported products, the certificate shall be issued by the authorized government agency in the country of origin, duly authenticated by the Philippine Consulate.	√ √ √	
10. Technical Specifications of Finished Product	√	√
11. Certificate of Analysis of Finished Product (from the same batch or lot of the representative sample submitted)	√	√
12. Master Manufacturing Procedure, Production Equipment, Sampling and In-Process Controls, and Master Packaging Procedure	√	
13. Identity and Purity Tests including Assay (if applicable)	√	
14. Stability Studies a) Accelerated - at least 6 months data, minimum of 2 batches at 40°C±2°C/75%RH±5% RH b) Real Time - at least 12 months data, minimum of 2 batches at 30°C±2°C/75%RH±5%RH c) For products intended to be stored in a refrigerator c.1) Accelerated - at least 6 months data, minimum of 2 batches, 25°C±2°C/60%RH±5%RH c.2) Real Time - at least 12 months data, minimum of 2 batches, 5°C±3°C	√ √	√ √
15. Representative Sample in market or commercial presentation (at least 1 year before expiry)	√	√
16. Labeling Materials a) Facsimile labels with actual color text (3 copies) b) Actual/Commercial labeling materials (3 copies)	√	√
17. For Imported Products (an English translation shall accompany any document not written in English) - Original Certificate of Traditionally-Used Herbal Product (or its equivalent) from the country of manufacture (issued at least 1 year from the date the application for registration was filed) - For countries not issuing the above, the following may be accepted: a) Government Certificate attesting the Registration Status of the Manufacturer, duly authenticated by the Philippine Consulate b) Certificate of Free Sale from the country of origin, duly authenticated by the Philippine Consulate. For products not freely sold in the country of origin, original Certificate of Traditionally-Used Herbal Product (or its equivalent) from a country where the product is freely sold shall be submitted.	√ √ √ √	
18. For Liquid and Semi-solid Products in Plastic Container or in Special Packaging Materials, refer to Annex C of A.O. ___ s. 2004.	√	
19. Evidence of Safety (based on documentation of prolonged and apparently uneventful use of the traditionally-used herbal product, and the absence of unsuspected potential for sytematic toxicity, carcinogenicity and teratogenicity)	√	
20. Evidence of Claimed Application (based on medical/ pharmaceutical literature or similar sources or a documentation of the knowledge on the application of such product through medical, historical, and ethnological documents)	√	

*Any changes, revisions or modifications shall require prior approval from the BFAD.

ANNEX D

CHECKLIST for REGISTRATION of HERBAL MEDICINES*

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Letter of Application as B.C. No. 01 s. 2002	√	√
2. Form No. 8 (Revised)	√	√
3. Copy of valid Certificate of Brand Name Clearance	√	
4. Copy of valid agreement between the manufacturer & trader/distributor/importer/exporter	√	
5. a) Copy of latest Certificate of Product Registration		√
b) For A.O. No. 54 - valid original Certificate of Product Registration	√	
6. Copy of valid LTO of the manufacturer/trader/importer/distributor, reflecting the product source(s)	√	√
7. Unit Dose and Batch Formulation	√	√
8. Technical Specifications of ALL Raw Materials	√	
9. Certificate of Analysis of Active Raw Material		
a) From the supplier of the active raw material (if applicable)	√	
b) From the manufacturer of the finished product	√	
c) Certification of Authenticity of Plant Specimen from the National Museum (Philippines) or any BFAD-recognized taxonomist	√	
In case of imported products, the certificate shall be issued by the authorized government agency in the country of origin, duly authenticated by the Philippine Consulate.		
10. Technical Specifications of Finished Product	√	√
11. Certificate of Analysis of Finished Product (from the same batch or lot of the representative sample submitted)	√	√
12. Master Manufacturing Procedure, Production Equipment, Sampling and In-Process Controls, and Master Packaging Procedure	√	
13. Identity and Purity Tests including Assay (if applicable)	√	
14. Stability Studies		
a) Accelerated - at least 6 months data, minimum of 2 batches at 40°C±2°C/75%RH±5% RH	√	
b) Real Time - at least 12 months data, minimum of 2 batches at 30°C±2°C/75%RH±5%RH		√
c) For products intended to be stored in a refrigerator		
c.1) Accelerated - at least 6 months data, minimum of 2 batches, 25°C±2°C/60%RH±5%RH	√	
c.2) Real Time - at least 12 months data, minimum of 2 batches, 5°C±3°C		√
15. Representative Sample in market or commercial presentation (at least 1 year before expiry)	√	√
16. Labeling Materials		
a) Facsimile labels with actual color text (3 copies)	√	
b) Actual/Commercial labeling materials (3 copies)		√
17. For herbal medicines validated by the NIRPROMP of the PCHRD, a copy of Memorandum of Agreement between the NIRPROMP & the applicant shall be submitted. Otherwise, a copy of approval of BFAD Committee on the registration of the said herbal medicine shall be submitted.	√	
18. For Imported Products (an English translation shall accompany any document not written in English)		
- Original Certificate of Pharmaceutical Product from the country of manufacture (issued at least 1 year from the date the application for registration was filed)	√	
- For countries not issuing CPP, the following may be accepted:		
a) Government Certificate attesting the Registration Status of the Manufacturer, duly authenticated by the Philippine Consulate	√	
b) Certificate of Free Sale from the country of origin, duly authenticated by the Philippine Consulate.	√	
For products not freely sold in the country of origin, original CPP from a country where the product is freely sold shall be submitted.		
19. For Liquid and Semi-solid Products in Plastic Container or in Special Packaging Materials, refer to Annex C of A.O. ___ s. 2004.	√	
20. Evidence of Safety and Efficacy		
a) Acute Lethal Dose 50 (LD_{50}), No-Adverse-Effect Level/Dose and Toxidrome	√	
b) Pharmacologic Effects in Animals both *In Vivo* and *In Vitro* Studies	√	
c) Bioassay (when applicable)	√	
d) Non-Mutagenicity - including Ames Test and Micronucleus Test	√	
e) Subchronic/ Chronic Toxicity Test	√	
f) Phase I Clinical Trial (for galenical products)	√	
g) Phases I, II & III Clinical Trials (for products in pharmaceutical dosage form)	√	

*Any changes, revisions or modifications shall require prior approval from the BFAD.

QWP 006-050-08 Annex 1 **Requirements of Products for Automatic Renewal** ***(Bureau Circular No. 2006-005 and 2006-007)*** ***(applicable only to those products without conditions at the back of the CPR)***	
☐	1. Completely filled up Assessment Slip (for Food)
☐	2. Notarized Application Letter specific for Automatic Renewal (AR)
☐	3. A copy of the revalidated BFAD License to Operate
☐	4. One (1) actual loose label attached in the documents
☐	5. Original copy of the Certificate of Product Registration (CPR)
☐	**6. Additional requirement as per Bureau Circular No. 2007-06: (for IMPORTED PRODUCTS only)** Original copy of the Certificate of Free Sale (CFS) issued by the Government Regulatory Agency in the country of origin stating that the specific products applied for registration are freely sold in the country of origin and fit for human consumption. (For products applied as initial registration on or before 2008)
☐	7. One (1) sample in commercial presentation
	NOTE: All documents must be secured in a folder according to the checklist of requirements. A color coded tag (size 5" x8") must be attached on the front side of the folder: Green (Imported product), Yellow (locally manufactured products), Red (products for re-application), Blue (products for Automatic Renewal). Folders must be in an expandable plastic envelope.
Registration **is strictly on Mondays only between 8:00am to 3:00pm at Room 101. Follow-up is strictly every Monday only at PSD Annex Bldg. Look for the Officer of the Day.** For more inquiries, please call Product Services Division Food Section at 857-19-00 local 8112. Address: **FDA-Food and Drug Administration Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa** Website: **www.fda.gov.ph**	
	Evaluator: _____ (initials and date)

QWP 006-050-02 Annex 2 **Requirements for Category 1 locally manufactured products and Category 2 Local and Imported products**	
☐	Completely filled up Assessment Slip (for Food)
☐	Notarized Application Letter
☐	A Copy of a revalidated BFAD License to Operate
☐	Product Information: i. List of ingredients in decreasing order of proportion. For additives with prescribed limit, the amount must be indicated. ii. Safety Certificate from flavor supplier iii. Finished product specification - (Physical, Chemical and Microbiological)
☐	One (1) sample in commercial presentation
☐	Labels and labeling materials used in the product (to be attached in the documents).
☐	Certificate of Analysis of the finished product. Indicate the analytical method used. Submit the test results, which are critical to the product.
☐	Flow diagram of method of manufacture, packaging and quality control
☐	A packaging certification of suitability for food use
☐	Estimated shelf life, parameters used and methods for determining shelf life complete with the ff: a. Product name, Batch number, Production date and dates of analysis b. Tabulated data & results in terms of physical, chemical and/or microbiological c. Conclusion as to the shelf life of the product d. Name and signature of the QA Analyst & QA Manager
☐	Justification of label claim(s) (if applicable)
☐	For locally manufactured food product, download the applicable Philippine National Standard for your specific product.
☐	For bottled water, download A.O. 18-A s. 1993 for additional tests to be submitted
☐	Previous Certificate of Product Registration (CPR) for Renewal Only
☐	Additional requirement as per Bureau Circular No. 2007-06: **(for IMPORTED PRODUCTS only)** Original copy of the Certificate of Free Sale (CFS) issued by the Government Regulatory Agency in the country of origin stating that the specific products applied for registration are freely sold in the country of origin and fit for human consumption.
	NOTE: All documents must be secured in a folder according to the checklist of requirements. A color coded tag (size 5" x8") must be attached on the front side of the folder: Green (Imported product), Yellow (locally manufactured products), Red (products for re-application), Blue (products for Automatic Renewal). Folders must be in an expandable plastic envelope.
Registration **is strictly on Mondays only between 8:00am to 3:00pm at Room 101. Follow-up is strictly every Monday only at PSD Annex Bldg. Look for the Officer of the Day.** For more inquiries, please call Product Services Division Food Section at 857-19-00 local 8112. Address: FDA-Food and Drug Administration Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa Website: www.fda.gov.ph	
	Evaluator: _____ (initials and date)

QWP 006-050-04 Annex 2 **Requirements for Food Supplement Local and Imported products**	
☐	Completely filled up Assessment Slip (for Food)
☐	Notarized Application Letter
☐	A Copy of a revalidated BFAD License to Operate, the source of the product must be reflected.
☐	Product Information: i. List of ingredients in decreasing order of proportion. For additives with prescribed limit, the amount must be indicated. ii. Safety Certificate from flavor supplier iii. Finished product specification (Physical, Chemical and Microbiological)
☐	One (1) sample in commercial presentation
☐	Labels and labeling materials used in the product (to be attached in the documents). Sticker of Importer (For Imported Products Only)
☐	Certificate of Analysis of the finished product-current or during the year. Indicate the analytical method used. Submit the test results, which are critical to the product. In house or conducted by FDA recognized laboratories e.g. UP, SGS, ITDI, PIPAC and FDC.
☐	Flow diagram of method of manufacture, packaging and quality control
☐	A packaging certification of suitability for food use
☐	Estimated shelf life, parameters used and methods for determining shelf life complete with the ff: a. Product name, Batch number, Production date and dates of analysis b. Tabulated data & results in terms of physical, chemical and microbiological c. Conclusion as to the shelf life of the product d. Name and signature of the QA Analyst & QA Manager
☐	Justification of label claim(s) (if applicable)
☐	Additional requirement may apply as necessary such as: a. Technical specifications of an ingredients(s) b. Computation c. Test results d. Rationale e. Scientific Study f. Pertinent regulations (local & international) g. Certificates (membership to an association, quarantine, free sale, etc. h. Other supporting documents i. Vitamin/ Mineral assay j. Safety date (toxicity study, LD50) • General test for steroids and alkaloids • Test for absence of synthetic substances such as: ➢ Aspirin ➢ Gonadal hormone ➢ Paracetamol ➢ Ephedrine & Pseudo-Ephedrine ➢ Dipyrone ➢ Fenfluramine ➢ Phenylbutazone ➢ Phetatermire ➢ Pyrazolone ➢ Methamphetamine ➢ Corticosteroid ➢ Vitamin B-Complex ➢ Anabolic Steroids ➢ Pesticide residue
☐	Previous Certificate of Product Registration (CPR) for Renewal Only
☐	Additional requirement as per Bureau Circular No. 2007-06: (for IMPORTED PRODUCTS only) Original copy of the Certificate of Free Sale (CFS) issued by the Government Regulatory Agency in the country of origin stating that the specific products applied for registration are freely sold in the country of origin and fit for human consumption.
	NOTE: All documents must be secured in a folder according to the checklist of requirements. A color coded tag (size 5" x8") must be attached on the front side of the folder: Green (Imported product), Yellow (locally manufactured products), Red (products for re-application), Blue (products for Automatic Renewal). Folders must be in an expandable plastic envelope.
Registration is strictly on Mondays only between 8:00am to 3:00pm at Room 101. Follow up of application is strictly every Monday only at the Annex Bldg. Look for the Officer of the Day For more inquiries, please call Product Services Division **Food Section at 857-19-00 local 8112.** Website: **www.fda.gov.ph**	

QWP 006-050-01 Annex 3 Requirements for Category 1 Imported Products (Bureau Order No. 163 s. 1997)	
☐	Completely filled up Assessment Slip (for Food)
☐	Application Letter
☐	A Copy of a revalidated BFAD License to Operate (LTO) with list of source(s)
☐	Notarized Affidavit of Undertaking
☐	Completely filled-up Product List
☐	Proforma/Sales Invoice declaring the products imported and applied for product registration
☐	One (1) sample in commercial presentation with sticker reflecting the complete name and address of the Importer.
☐	One (1) actual loose label attached in the documents with sticker reflecting the complete name and address of the Importer.
☐	Additional requirement as per Bureau Circular No. 2007-06: Original copy of the Certificate of Free Sale (CFS) issued by the Government Regulatory Agency in the country of origin stating that the specific products applied for registration are freely sold in the country of origin and fit for human consumption.
	NOTE: All documents must be secured in a folder according to the checklist of requirements. A color coded tag (size 5" x8") must be attached on the front side of the folder: Green (Imported product), Yellow (locally manufactured products), Red (products for re-application), Blue (products for Automatic Renewal). Folders must be in an expandable plastic envelope.
Registration is **strictly on Mondays only between 8:00am to 3:00pm at Room 101. Follow-up is strictly every Monday only at PSD Annex Bldg. Look for the Officer of the Day.** For more inquiries, please call Product Services Division Food Section at 857-19-00 local 8112. Address: **FDA-Food and Drug Administration Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa** Website: www.fda.gov.ph	
	Evaluator: _____ (initials and date)