GOVERNMENT OF THE REPUBLIC OF THE UNION OF MYANMAR

Ministry of Health

Department of Food and Drug Administration

A Guideline on Drug Registration Application

(April,2014)

GOVERNMENT OF THE REPUBLIC OF THE UNION OF MYANMAR

Ministry of Health

Department of Food and Drug Administration

Ref: DAC/RM/001/14(G)

Date : 22nd April, 2014

Initial application for Registration

1. An application for registration of drug must be submitted to the Department of Food and Drug Administration in the original prescribed form (Form 1 Registration). Form(1) is available at one thousand kyats each at office of the Department of Food and Drug Administration, Naypyitaw and Yangon.

2. Separate registration has to be applied for pharmaceutical preparations of different strength or different dosage form.

3. Form 1 must be filled out in type print (or) (written with capital letter) attached with computer print. Enclosures submitted together with application form shall be marked with proper reference. **A form which is filled incompletely or improperly will not be accepted.**

4. Form(1) must also be accompanied with two sets of documents on complete information of drugs. (See Annex-I for type of documentation required). One copy must be kept in company office. Documents have to be submitted in file in an order as listed in "Documents Required for Registration of Drugs". A list of documents submitted should be shown on the first sheet of the file.

5. **An application with incomplete documentation will not be accepted.**

6. (a) An application must be submitted in person by an authorized representative of owner of drug * Any application made by mail or facsimile or means other than in person, will not accepted. An authorized representative has to be a resident in Myanmar.

(b) Should an authorization for representation be granted to the local company, the representative shall be a company employee technical competent person authorized to serve as a contact person.

7. Registration assessment fees; 300000 Kyats must have been remitted to MD account of Department of Food & Drug Administration when submission of the application form is made.

8. (a) If it is an application for registration of drugs manufactured outside Myanmar, the Food and Drug Administration will issue " Approval for importation of Drug Samples" (Annex II) after receiving application. The drug samples as specified in the approval shall then be imported into the country. The holder of the approval shall comply not only with the conditions stipulated in (*Product licence holder at county of origin).

(b) A per Ministry of Health Notification 3/93 dated 5-8-93 paragraph 5, prior approval shall be obtained from Food and Drug Administration for importation of registration sample drug.

For the importation of sample drug without prior approval of the FDA, the FDA will not issue approval certificate.

9. (a) The following kind of drug samples are normally required.

- Samples for laboratory analysis
- Samples for retention
- Only for new products of Myanmar that need to conduct the clinical trial.

(b) For the total numbers of sample drugs to be submitted, please refer to " Required quantities of sample drugs for registration" (Annex III)

(c) All drug samples must be accompanied with their respective analytical report (the certificate of analysis). The name and designation of an official who signs the report must be stated. **The photocopy of report is not acceptable.**

10. The evaluation process for registration will be started only when all the requirements for registration application have been met; viz (a) remittance of registration Assessment Fees, (b) complete set of documents, (c) sufficient quantity and good shelf life of drug samples.

11. (a) When the drug is approved for registration, the applicant will be notified to remit 500000 Kyats as Registration Fees. The notification will be made only on the notice board of FDA.

*(b) **Failure to remit Registration Fees within 90days from the date of intimation will constitute forgoing of an application by an applicant.** If so happens, neither the Registration Assessment Fees remitted nor registration documents and drug samples will be returned.

*12. **Failure to make a follow-up of an application by an applicant for more than six months from the date of remittance of assessment fees, will be taken as forgoing of an application.**

13. The Registration Certificate (Form II) will be issued only when the acknowledgement of receipt of payments issued by FDA is submitted.

14. The submitted dossiers are not reclaimable in case of rejection of application.

Updating Changes to registered drugs

1. Updating Changes to registered drugs shall be made only with the approval of Department of Food and Drug Administration.

2. For this purpose, the holder of Registration Certificate shall apply for variation of Registration; to FDA, Stating

   (a) reason for change.

   (b) relevant data or findings from studies on which is based the justification of change.

   (c) significant effect of changes to the specifications of drug.

3. The following shall be submitted together with the application:

(a) The attestation by country's drug regulatory authority to approval of such changes. If the regulatory authority's attestation cannot be provided, explain the reason for it.

(b) A photo copy of Drug Registration Certificate.

4. (a) When it is decided to approve of changes, 100000 Kyats (Per one type of change) fees will be levied on an applicant. The Drug Advisory Committee may waive this requirement if it believes that change is of benefit to public as regards quality, safety and efficacy of drugs.

(b) An original Registration Certificate must then be submitted to make approved amendments on the certificate.

Renewal of Registration

1. Application for renewal of registration shall be submitted **90days** before the validity of the registration terminates. Failure to adhere to the 90days requirement may result in disruption of continued validity of registration.

2. Application shall be submitted in the same manner as prescribed for application for registration of drug.

3. The drug samples for clinical trial are normally not required. The samples for laboratory analysis and for retention are still required. Please refer to " Required quantities of sample drug for analysis and retention". (Annex IV)

4. The documentary requirement is the same as that of an initial application (See Type of documents required for registration Annex I). Information provided, however, has to be updated. New findings which had not been submitted in an initial application have to be submitted too.

5. Registration Assessment fees must have been remitted to FDA at the time of application of renewal of registration. When the renewal of

registration. When renewal of registration is approved of , 500000 Kyats must be remitted as Registration Fees.

6. Upon approval of renewing, new Registration Number will be designed, which shall make the Old Registration Number void.

7. ***Failure to apply for renewal of registration with effect from the date of expiry of the certificate.**

Fees Levied

1.Registration Assessment Fees **300000** Kyats + Fees (in kyats) for Laboratory analysis

2.Registration Fees 500000 Kyats

3.Variation of Registration 100000 kyats for each variation

Note: (1)&(2) are levied either for New (fresh) registration or renewal of registration.

Registration of Active Pharmaceutical Raw Materials

1. Documentary requirements

A. Administrative Documents

1. A certificate of product issued by the regulatory authority of its own country that the product is authorized to be sold in country of origin.

2. (a) Properly endorsed photocopy of valid manufacturing License.

(b) GMP certificate of manufacturing plant.

3. A letter of authorization for legal representation of manufacturer (owner of product) in Myanmar.

4. A business registration certificate of local representatives.

B. Pharmaceutical Documents

1. Generic name
2. Chemical name
3. Empirical & Structural Chemical formula
4. Pharmacopoeia to which the product conforms.
5. Pharmaceutical specifications (including physical characteristics, solubility, identification, loss on drying, Sulphated, ash, heavy metal, purity, assay, etc.)
6. Method of analysis
7. Manufacturing process
8. Quantity Assurance System (including control of starting material, in-process control, finished raw material control, packaging control, etc.)
9. Certificate of analysis.
10. Stability test report of at least three different batches.
11. Recommended Shelf-Life.
12. Recommended Storage conditions.
13. Packaging specifications.

2. Fees

(a) Assessment feesKyats - 300000

(b) Registration feesKyats - 500000

(c) Variation fees Kyats - 100000

3. Application shall be made in the same manner as prescribed for registration application of finished product.

4. A sample (20gm) has to be submitted together with the dossier. The sample must be packed & labeled properly. An approval of FDA for importation of sample raw material is also required.

THE ASEAN COMMON TECHNICAL DOSSIER (ACID) FOR THE REGISTRATION OF PHARAMACEUTICALS FOR HUMAN USE

PATR I : ADMINISTRATIVE DATA AND PRODUCT INFORMATION

1. Application Form

2. Letter of Authorisation

3. Certification

3.1 For contract manufacturing

(a) License of pharmaceutical industries and contract manufacturer

(b) Contract manufacturing agreement

(c) Copy of "under-license" agreement

3.3 For imported products

(a) License of pharmaceutical industries/ importer/ wholesaler (country specific)

(b) Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format.

(c) Site master file of manufacturer (unless previously submitted within the last 2years) (country specific)

4. Labelling

4.1 United Carton

4.2 Inner Label

4.3 Blister/Strips

5. Product Information

5.1 Package insert (package insert is required for generic products)

5.2 Summary of Product Characteristic (Product Data Sheet) (required for NCE & Biotechnology products)

5.2.1 Name of the Medicinal Product

(a) Product Name

(b) Strength

(c) Pharmaceutical Dosage Form

5.2.2 Quality and Quantitative Composition

(a) Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by this salt or hydrate form if relevant

(b) Quantitative Declaration The quantity of the active substance must be expressed per dosage unit

5.2.3 Pharmaceutical Form Visual description of the appearance of the product (colour, markings.etc)e.g: "Table White, circular flat beveled edge tablets marked '100' on one side

5.2.4 Clinical Particulars

(a) Therapeutic indications

(b) Posology and method of administration

(c) Contraindications

(d) Special warning and precautions for use

(e) Interaction with other medication products and other forms of interactions

(f) Pregnancy and lactation

(g) Effects on ability to drive and use machine

(h) Undesirable effects

(i) Overdose

5.2.5 Pharmacological Properties.

(a) Pharmacodynamic Properties

(b) Pharmacokinetic Properties

(c) Preclinical safety Data

5.2.6 Pharmaceutical Particulars

(a) List of excipients

(b) Incompatibilities

(c) Shelf life

Shelf life of the medicinal product as packages for sale. Shelf life after dilution or reconstitution according to directions. Shelf-life first opening the container

(d) Special precautions for container

(e) Nature and contents of container

5.2.7 Marketing Authorization Holder

5.2.8 Marketing Authorization Number

5.2.9 Date of first authorization/ renewal of the authorization

5.2.10 Date of revision of the text

5.3 Patient Information Leaflet (PIL) (PIL is required for Over-the Counter Products)

Part II Quality

S. Drug Substance

SI General Information

SI.1 Nomenclature

- Information from the SI

SI.2 Structure

- Structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass.

SI.3 General Properties

- Physico chemical characteristics and other relevant properties including biological activity for biotech.
- Schematic amino acid sequence indicating glycosylation sites or the post-translational modifications and relative molecular mass as appropriate.

S2 Manufacture

S2.1 Manufacturer (s)

- Name and address of the manufacturer (s).

S2.2 Description of Manufacturing Process and Process Controls.*

S2.3 Control of Materials.*

- Starting materials, solvents, reagents, catalysts and any other materials used in the manufacture of the drugs substance indicating where each material is used in the process, Tests and acceptance criteria of these materials.
- Control of source and starting materials of biological origin.
- Source, history and generation of the call substrate
- Cell banking system, characterization and testing.
- Viral safety evaluation.

S2.4 Control of Critical Steps and Intermediates

- Critical steps : Test and acceptance criteria, with justification including experimental data. *performed at critical steps of the manufacturing process to ensure that the process is controlled.
- Intermediates : Specifications and analytical procedure, if any, for intermediates isolated during to process.*

S2.5 Process Validation and/ or Evaluation.*

- Process Validation and/ or evaluation studies for aseptic processing and sterilization.

S2.6 Manufacturing Process Development.*

- Description and discussion of significant changes made to the manufacturing process and/or manufacturing site of the drug substance used in producing non-clinical, clinical, scale-up pilot and if available, production scale batches.
- The development history of the manufacturing process as described in S2.2

S3 Characterisation.*

*** required for NCE (New Chemical Entity)/ New products for Myanmar.**

S3.1 Elucidation of Structure and other characteristics

- Confirmation of structure based on e. g synthetic route and spectral analyses.
- Compendial requirement or appropriate information from the manufacturer
- Details on primary, secondary and higher-order structure and information on biological activity, purity and immunochemical properties (when relevant).

S3.2 Impurities*

- Summary of impurities monitored or tested for during and after manufacture of drug substance.
- Compendial requirements or appropriate information from the manufacture of drug substance.

S4. Control of Drug Substance

S4.1 Specification*

- Detailed specification, test and acceptance criteria.
- Compendial specification or appropriate information from the manufacturer

- Specify source, including as appropriate species of animal, type of microorganism etc..

S4.2 Analytical Procedures*

- The analytical information, including experimental data for the analytical procedures used for testing of drug substance.
- Non-compendial methods

S4.4 Batch Analyses*

- Description of batches and results of the analysis to establish the specification.

S4.5 Justification of Specification*

- Justification for drug substance specification.*

S5. Reference Standard or Materials,*

- Information on the reference standards of reference materials used for testing of the drug substance.*
- Compendial reference standards

S6 Container Closure System*

S7 Stability

- Stability report.*
- Literature data

P DRUG PRODUCT

P1 Description and Composition

Description

- Dosage form and characteristics
- Accompanying reconstitution diluents(s) if any.
- Type of container and closure used for the dosage form and reconstitution diluent, if applicable.

Composition

- Name quality stated in metric weight or measures, function and quality

P2.1 Information on Development Studies.*

- Data on the development studies conducted to establish that the dosage from, Formulation, Manufacturing process, container closer system.

P2.2 Components of the Drug Product

P2.2.1Active ingredient

- Justification of the compatibility of the active ingredient with excipients Lised in P1

  In the case of combination products, justification of the compatibility of active ingredients with each other.*

- Literature data.

*** required for NCE (New Chemical Entity)/New products for Myanmar.**

P2.2.2Excipients*

- Justification of the choice of excipients used in P1. Which may influence the drug product performance.

P2.3 Finished Product

P2.3.1Formulation Development

- A brief summary describing the development of the finished product (taking into consideration the proposed route of administration and usage for NCE and Biotech)

P2.3.2 Overages

- Justification of any overage in the formulation(s) described in P1.

- Physicochemical and Biological Properties

Parameters relevant to the performance of the finished product e. g pH, dissolution.

P2.4 - Manufacturing Process Development

- Selection and optimization of the manufacturing process.
- Differences between the manufacturing process(es)used to produce pivotal clinical batches and the process described in P.3.2, if applicable.*

P2.5 - Container Closure System

- Suitability of the container closure system used for the storage, transportation(shipping) and use of the finished product.

P2.6 - Microbiological Attributes

- Microbiological attributes of the dosage form, where appropriate.

P2.7 - Compatibility

- Compatibility of the finished product with reconstitution diluents(s) or dosage devices. Literature data.*

P3 Manufacture

P3.1 Batch Formula

- Name and quantities of all ingredients.

P3.2 Manufacturing Process and Process Control.

- Description of manufacturing process and process control.

P3.3 Control of Critical Steps and Intermediates

- Tests and acceptance criteria

P3.4 Process Validation and/or Evaluation

- Description documentation and results of the validation and evaluation studies for critical steps or critical assays used in the manufacturing process.

P4 Control of excipients

P4.1 - Specifications for excipients*

- Compendial requirement or appropriate information from the manufacturer.

P4.2 Analytical Procedures used for testing excipients where appropriate.

- Compendial requirements or appropriate information from the manufacture.

P4.3 Excipient of Human or Animal Origin Information regarding sources and or adventious agents*.

- Compendial requirements or appropriate information from the manufacturer.

P4.4 Novel Excipients*

- For excipient(s) used for the first time in a finished Product or by a new route of administration, full details of manufacture, characterization.

P5 Control of Finished Product

P5.1 Specification

- The specification(s) for the finished product.

P5.2 Analytical Procedures

- Analytical procedures used for testing the finished product.

P5.3 Validation of Analytical Procedures

- Information including experimental data for the analytical procedure used for testing the finished product*
- Non Compendial Method.

* required for NCE (New Chemical Entity)/New products for Myanmar.

- Verification of compendia method applicability – precision & accuracy.

P5.4 Batch Analyses

- Description and test results of all relevant batches.

P5.5 Characterisation of Impurities

- Information of the characterization of impurities.*
- Compendial requirements or appropriate information form the manufacturer

P5.6 Justification of Specification(s)

- Justification of the Proposed finished product specification.

P6 Container Closure System

- Specification and control of primary and secondary packaging material, type of packaging & the package size, details of packaging inclusion (e. g desiccant, etc.)

P8. Stability

- Stability report : data demonstrating that product is stablet through its proposed shelf life.
- Commitment on post approval stability monitoring.

P9 Product Interchangeability (Generic only)

Equivalence evidence

- In Vitro

  Comparative dissolution study as required.

- In Viro

  Bioequivalence study as required.

Part III : NONCLINICAL (for NCE/New products for Myanmar).

1. General Aspect

2. Content and structural format

1. Nonclinical Written Summaries

1.1 Pharmacology

1.1.1 Primary Pharmacodynamics

1.1.2 Secondary pharmacodynamics

1.1.3 Safety Pharmacology

1.1.4 Pharmacodynamics Drug Interactions.

1.2 Pharmacokinetics

1.2.1Absoeption

1.2.2 Distribution

1.2.3 Metabolism

1.2.4Excretion

1.2.5 Pharmacokinetics Drug Interaction (non-clinical)

1.2.6 Other Pharmacokinetics Studies

1.3 Toxicology

1.3.1 Single dose toxicity

1.3.2 Repeat dose toxicity

1.3.3 Genotoxicity

1.3.4 Carcinogenicity

1.3.5 Reproductive and developmental toxicity

1.3.5.1 Fertility & early embryonic development

1.3.5.2 Embryo-fetal development

1.3.5.3 Prenatal and postnatal development

1.3.6 Local tolerance

1.3.7 Other toxicity studies, if available

- Antigenicity
- Immunotoxicity

- Dependence
- Metabolites
- Impurities

Part IV Clinical (for NCE/ New Product for Myanmar)

"Clinical Overview"

1. Product Development Rationale
2. Overview of Biopharmaceutics
3. Overview of Clinical Pharmacology
4. Overview of Efficacy
5. Overview of Safety
6. Benefits and Risk Conclusions

- "Clinical Summary"

1. Summary of Biopharmaceutic Studies and Associated Analytical Method

1.1 Background and Overview

1.2 Summary of Resuts of Individual Studies

1.3 Comparison and Analyses of Result Across Studies

2. **Summary of Clinical Pharmacology Studies**

2.1 Background and Overview

2.2 Summary of Results of Individual Studies

2.3 Comparison and Analyses of Results Across Studies

2.4 Special Studies

3. **Summary of Clinical Efficacy**

3.1 Background and Overview of Clinical Efficacy

3.2 Summary of Results of Individual Studies

3.3 Comparison and Analyses of Results Across Studies

3.4 Analysis of Clinical Information Relevant to Dosing Recommendations

3.5 Persistence of Efficacy and/or Tolerance Effects.

4. Summary of Clinical Safety

4.1 Exposure to the Drug

4.2 Adverse Events

4.3 Clinical Laboratory Evaluations

4.4 Vital Sign, Physical Findings, and Other Observations Related to Safety

4.5 Safety in Special Groups and Situations

4.6 Post-marketing Data

5. Synopses of Individual Studies

"Clinical Study Reports" (if applicable)

1. Reports of Biopharmaceutic Studies
1.1 B A study Reports
1.2 Comparative BA or BE Study Reports
1.3 In vitro-In vivo Correlation Study Reports
1.4 Reports of Bioanalytical and Analytical Methods for Human Studies

2. Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials

2.1 Plasma Protein Binding Study Reports

2.2 Reports of Hepatic Metabolism and Drug Interaction Study

2.3 Reports of Studies Using Other Human Biomaterials

3. Report of Human Pharmacokinetic (PK) Studies

3.1 Healthy Subject PK and Initial Tolerability Study Reports

3.2 Patient PK Initial Tolerability Study Reports

3.3 Population PK Study Reports

4. Reports of Human Pharmacodynamic (PD) Studies

4.1 Healthy Subject & PD and PK/PD Study Reports.

4.2 Patient PD and PK/PD Study Reports.

5. Reports of Efficacy and Safety studies

5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication

5.2 Study Reports of Uncontrolled Clinical Studies

5.3 Reports of Analyses of Data from More Than One Study, Including Any Formal integrated Analyses, Meta-analyses & Bridging Analyses

5.4 Other Clinical Study Reports

6. Reports of Post-Marketing Experience

7. Case Report Forms and Individual Patient Listing

8. List of Key Literature References*

Well- established Drug Products. (WHO)

Pharmaceutical Product that contain well established drugs & which:

- Pharmaceutical Product that contain well established drugs & which:

  - have been marketed for at least five years that undertake active post marketing monitoring;

- have been widely used in sufficiently large number of patients to permit the assumption that safety & efficacy are well known, have the same route of administration & strength & the same or similar indication as in those countries.

Department of Food & Drug Administration

Registration of Food Supplement

1. The Procedure of registration for Food Supplement is the same as Pharmaceuticals

2. The List of documents required for Food Supplement are followings.

Administrative data

(a) Letter of Authorisation

(b) Free Sale Certificate (original) issued by the competent authority in country or origin.

(c) Properly endored/ Legalization of Manufacturing License copy

(d) ISO Certificate (Standard)

Quality

(a) Raw Specification, Source of raw material

(b) Raw quality control

(c) Master Formula

(d) Manufacturing process

(e) Finish product specification

(f) Reference Text

(g) Certificate of Analysis (Finish product)

(i) Stability test of finish product

Safety & efficacy data

(a) Action of Active Ingredient ; (Reference Text)

(b) Safety data of finish Product

(c) Research Paper/ Literature of Food Supplement

(approved by International Reconized Research Institute)

Documents required for Registration of Vaccines

I. Administrative data and product information same as Pharmaceuticals

- Batch release certificate of regulatory authority
- WHO prequalification certificate
- Summary of product characteristic

II. Manufacturing and Quality

- Detailed composition of the product

  (Description, Characterization, Biological activity test)

- Description of manufacturing facility

  (Identification, Manufacture of other products, Layout, Precaution against contamination)

- Method of Manufacture

  (Description of the seed lot and cell substrate systems used, synthesis pathway and flow chart of manufacturing process)

- Detailed description of source of raw materials

  (e. g virus sources, animal sources, DNA recombinant products, host cell, gene construct, vector etc, cell bank system, cell growth and harvesting, purification and inactivation processing)

- Process Controls

  (In process controls, Process validation)

- Manufacturing consistency (minimum of 3 consecutive batches)
- Immunogenic substance specifications
- Reprocessing

  (In event of rejection of the lot or batch by the Manufacturer's QA/QC)

- Stability of the active ingredient and finished product

(Real time and accelerated)

- Microbiological attributes
- Containers and closure system
- 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.
- Composition and characterization of final product including recipients, adjuvant and preservatives.

III. Report on pre-clinical studies

*For Established Biological Product only

- Phase IV clinical trial

* For Live vaccine

- Transmission to contact studies
- Vaccine induced disease studies
- Effect on large scale vaccination on the natural history of the disease

* For Combination of Biological Product

- Clinical data on Efficacy
- Clinical data on Satety

သက်ဆိုင်ရာသို့

To whom it may concern

အောက်ဖော်ပြပါပုဂ္ဂိုလ်သည်ဖော်ပြပါဆေးဝါးများအားမြန်မာနိုင်ငံတွင်မှတ်ပုံတင်ရန်လျှောက်ထားလာပါသဖြင့်လိုအပ်သောစမ်းသပ်မှုများဆောင်ရွက်ရန်ကျောဘက်တွင် ဖော်ပြထားသည့် ဆေးဝါးနမူနာများကို မြန်မာနိုင်ငံအတွင်းသို့ တစ်ကြိမ်တင်သွင်းခြင်းအား ထောက်ခံလိုက် သည်။

In order to carry out necessary tests on drugs which have been applied for registration in Myanmar, approval is hereby granted to under mentioned person to import one consignment of drug samples as specified in the attached schedule overleaf.

တင်သွင်းခွင့်ရရှိသူအမည်

Name of Person ……..

နိုင်ငံသားစိစစ်ရေးကတ်ပြားအမှတ်

NRC. No. ……..

လိပ်စာ

Address ……..

လုပ်ငန်းအမည်

Name of Consignor ……..

တင်ပို့သူအမည်

Name of Consignor ……..

လိပ်စာ

Address ……..

ခွင့်ပြုသည့်နေ့

Date of Approval ……..

ခွင့်ပြုသည့်ကာလ

Valid up to ……..

ခါတ်ပုံ

လက်မှတ် ……
Signature ……
ခွင့်ပြုသူအမည် ……
Name ……
ရာထူး ……
Destination ……

စည်းကမ်းချက်များပူးတွဲတင်ကြည့်ပါ

See conditions attached

နမူနာတင်သွင်းမည့်ဆေးဝါးများ

စဉ် Sr No.	ဆေးဝါးအမည် (အမှတ်တံဆိပ်အမည်/ မျိုးရိုးအမည်) Name of Drugs (trade name/ generic name)	ဆေးဝါးပုံသဏ္ဌာန် ပါဝင်မှုပမာဏ Dosage Form/ Strength	ထုပ်ပိုးပုံ Packing & Presentation	ရေတွက်ပုံ A/U	တင်သွင်းမည့် ဆေးဝါးပမာဏ	ထုတ်လုပ် စက်ရုံ/နိုင်ငံ Name of Manufacturer/ Country

စည်းကမ်းချက်များ

Conditions

၁။ ဤတင်သွင်းခြင်းထောက်ခံချက်(မူရင်း)သာတရားဝင်ဖြစ်သည်။ မည်သည့်ပုံစံမျိုးဖြင့် ဖြစ်စေ၊ မိတ္တူသည် တရားဝင်ထောက်ခံချက်မဟုတ်

This approval shall official only with use of original Approval Certificate. Copy in any from shall be avoid.

၂။ ဤဆေးဝါးနမူနာ တင်သွင်းခြင်းထောက်ခံချက်သည် တစ်ကြိမ်တင်သွင်းခြင်းကို ထောက်ခံခြင်းဖြစ်ပြီးဖော်ပြထားသော သတ်မှတ်ကာလအတွင်းတွင်သာ အကျိုးသက်ရောက် စေရမည်။

The approval shall be applicable for only consignment and shall be invalidated from the date stated on it.

၃။ ဤတင်သွင်းခြင်းထောက်ခံချက်သည် လက်မှတ်တွင်ဖော်ပြထားသည့်ပုဂ္ဂိုလ်အား ခွင့်ပြုခြင်းသာဖြစ်ပြီး အခြားတစ်ယောက်အား လွှဲပြောင်းခြင်းမပြုရ။

The approval is granted to a person as stated in the permit. This permit is not transferable to another person.

၄။ အသုံးမပြုသည့် တင်သွင်းခြင်းထောက်ခံစာအား တင်သွင်းခွင့်သက်တမ်းကုန်သည့်နေ့ မှစ၍ (၁)ပတ်အတွင်း အစားအသောက်နှင့် ဆေးဝါးကွပ်ကဲရေးဦးစီးဌာနသို့ ပြန်လည်အပ်နှံ ရမည်။

The unused approval must be returned to the Department of Food & Drug Administration within two days from date of expiry of the approval.

၅။ တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲပါဇယားပေါ်ပါ ဖော်ပြထားသော အချက်အလက်များအား ပြင်ဆင်ခြင်း၊ ဖောက်ဖျက်ခြင်း၊ မပြုလုပ်ရ။

No Change or deletion shall be made to any expression of the approval and of the attached schedule.

၆။ ဤတင်သွင်းခြင်းထောက်ခံစာအရ တင်သွင်းခဲ့သော ဆေးဝါးနမူနာများနှင့် တင်သွင်းခွင့်ထောက်ခံစာအား အစားအသောက်နှင့် ဆေးဝါးကွပ်ကဲရေးဦးစီးဌာန သို့ ဆိုက်ရောက်ရာဌာနမှ ထုတ်ယူပြီးသည့်နေ့မှစ၍ (၁)ပတ်အတွင်း ပေးပို့ရမည်။

The imported drug samples and the approval must be submitted to the Department to Food & Drug Administration within one week from the date of clearance from port of entry.

၇။ ပေးပို့သည့်ဆေးဝါးနမူနာသည်တင်သွင်းခြင်းထောက်ခံစာနှင့်ပူးတွဲပါဇယား အတိုင်းဖြစ်စေရမည်။ ကွဲလွဲချက်များဖြစ်ပေါ်ပါက တင်သွင်းခွင့်ရရှိသူမှ လုံးဝ တာဝန်ယူရမည်။

Submitted drug samples must be totally in compliance with specification stated in the schedule. The holder of the approval shall bear the responsibilities of any discrepancies.

၈။ အထက်ပါစည်းကမ်းချက်များအား လိုက်နာရန်ပျက်ကွက်ပါက တည်ဆဲ ဥပဒေများအရ အရေးယူခြင်းခံရမည်။

Failure to comply with above mentioned conditions, is liable to actions in accordance with existing rules and regulation laws.

၉။ ဤတင်သွင်းခြင်းထောက်ခံစာကိုင်ဆောင်သူသည် မှတ်ပုံတင်လျှောက်ထားရန်အတွက် ဆေးဝါးများတင်သွင်းရာတွင် တည်ဆဲအကောက်ခွန်စည်းမျဉ်းစည်းကမ်းလုပ်ထုံးလုပ်နည်းများကို လိုက်နာရမည်။

In importing sample drugs, holder of the approval shall comply with existing rules and regulations of Commerce and Customs departments.

DEPARTMENT OF FOOD & DRUG ADMINISTRATION

Required quantities of sample drugs for initial registration

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Dose	Syrup/ Suspension/ Elixir(up to 120 ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot.)
1	Anti-bacteria	1000	80	100	80 70
2	Anti-fungal	1000		100	70
3	Anti-viral	1000	80		70
4	Anti-malarial	1000		100	
5	Anti-tuberculous	1000		100	
6	Anti-amoebic	1000	80	100	60
7	Anthelmintic				

	(a) Single dose	150doses	80			
	(b) Multiple doses	150doses	80			
8	Anti-inflammatory	1000	80	100		
9	Anti-depressant	1000			100	
10	Anti-psychotic	1000			100	
11	Anti-convulsant	1000		80	100	
12	Anti-parkinsonism	1000				
13	Anxiolytic	1000			100	
14	Anti-diabetic	1000			100	
15	Anti-thyroid	1000				
16	Anti-emetic	1000		80	100	
17	Anti-diarrhoeal	1000				
18	Antispasmodic	1000			100	
19	Antacid	1000		80		
20	Anti-ulcer	1000		80	100	
21	Anti-asthmatic	1000		80	100	
22	Antitussive	1000		80		
23	Antihistamine	1000		80	100	
24	Mucolytic	1000		80	100	70
25	Anti-anginal	1000			100	
26	Anti-hypertensive	1000			100	
27	Anti-arrhythmic	1000			100	
28	Beta adrenergic blockers	1000			100	
29	Calcium Antagonnist	1000			100	

30	Diuretic	1000			100		
31	Anti-hyperlipidaemic	1000					
32	Anti-heamorrhoidal	1000					
*33	Ant-neoplastic	500			40	40	
34	Anti-migraine	1000	80		80		
35	An aesthetics*				80	50	100

*Antineoplastic from India must be submitted with own COA and Lab analysis Report from SGS India Pvt. Ltd., (India)

*Antineoplastic from other Countries must be submitted with own COA and Test result from accreditated Analytical Laboratory.

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Does	Syrup/ Suspension/ Ellixir(Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot).
36	Amino Acids	1500	80	80	60 (LVP) 100 (SVP)
37	Antianaemic	1500	80	100	
38	Contraceptive	200 cycles			
39	Corticosteroids	1000		100	100
40	Intravenous Replacement Fluids				60 (LVP) 100

					(SVP)
41	Plasma Expander				
42	I/V Glucose (10% 25% 50%)	100	"		
43	Multivitamin	1500	80	80	
44	Nootropic	1000		100	
45(a)	Oral Rehydration Salt tablets	700			
(b)	Oral Rahydration Salt Powder	200 Sachets (one liter pack) 400 Sachets (less than one Liter pack)			
46	Uricosurics	1000			
47	Vaccines			80	
48	Dermatologicals				100
49	Eye/ Ear Drops				100

LVP = Large Volume Parenteral, (500 ml & above) SVP = Small Volume Parenteral. (Less than 500 ml)

Note: (1) All the submitted sample drug must have a minimum of two years' shelf-life (or ¾ of * total shelf life)

(2) In case of large sized packed packs (e.g. 500's, liter pack or jar) the required amounts are 3 bottles.

(3) If more than one type of packaging or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remaining have to be submitted in a

minimum of four unit-pack each if it is a small sized pack and one unit-pack each if it is a large sized pack.

Annex IV

DEPARTMENT OF FOOD & DRUG ADMINISTRATION

Required quantities of sample drugs for renewal

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Does	Syrup/ Suspension/ Ellixir(Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot).
1	Anti-bacterial	300	20	30	20 15
2	Anti-fungal	300	20	30	15
3	Anti-viral	300	20	30	15
4	Anti-malarial	300		30	
5	Anti-tuberculous	300		30	
6	Anti-amoebic	300	20	30	20
7	Anthelmintic				
	(a) Single does	50	20		
	(b) Multiple doses	50	20		
8	Anti-inflammatory Drugs (Non-steroidal)	300	20	30	15
9	Anti-depressant	300	20	30	
10	Anti-psychotic	300	20	30	
11	Anti-convulsant	300	20	30	
12	Anti-parkinsonism	300	20	30	
13	Anxiolytic	300	20	30	

14	Anti-diabetic	300		30
15	Anti-thyroid	300		
16	Anti-emetic	300	20	30
17	Anti-diarrhoeal	300	20	
18	Antispasmodic	300	20	30
19	Antacid	300	20	
20	Anti-ulcer	300	20	30
21	Anti-asthmatic	300	20	30
22	Antitussive	300	20	
23	Antihistanmine	300	20	30
24	Mucolytic	300	20	
25	Anti-anginal	300		30
26	Anti-hypertensive	300		30
27	Anti-arrhythmic	300		30
28	Beta adrenergic blockers	300		30
29	Calcium Antagonist	300		30
30	Diuretic	300		30
31	Anti-hyperlipidaemic	300		
32	Anti-heamorrhoidal	300		
*33	Ant-neoplastic	100		10

* Antineoplastic from India must be submitted with own COA and Lab analysis Report from SGS India Pvt. Ltd., (India)

* Antineoplastic from other Countries must be submitted with own COA and Test result from accreditated Analytical Laboratory.

No	Drug Category	Required Quantities

		Tablets/ Capsules/ United Does	Syrup/ Suspension/ Ellixir(Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot).
34	Anti-migraine	300	20	30	
35	Anaesthetics*			30	20
36	Amino Acids	300			10(LVP)20 15 (SVP)
37	Antianaemic	300	20	50	
38	Cold Remedy	300	20		
39	Contraceptive	30 cycles			
40	Corticosteroids	300		30	
41	Intravenous Replacement Fluids				10 (LVP) 20 (SVP)
42	Multivitamin	300	20	50	
43	Nootropic	300	20	30	
44(a)	Oral Rehydration Salt tablets	100			
(b)	Oral Rahydration Salt Powder	30 Sachets (1 L pack) 50 Sachets (< one L pack)			
45	Uricosurics	300			
46*	Vaccines			30	

47	Dermatologicals	15
48	Eye/ Ear Drops	15

LVP = Large Volume Parenteral, (500 ml & above) SVP = Small Volume Parenteral. (Less than 500 ml)

Note: (1) All the submitted sample drug must have a minimum **one year of** shelf-life

(2) In case of large sized packs (e.g. 500'sm 1000's liter pack or jar) the required amounts are 2 bottles or boxes.

(3) If more than one type of packaging or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remainings have to be submitted in a minimum of one unit-pack.

Annex IV

DEPARTMENT OF FOOD & DRUG ADMINISTRATION

Required quantities of sample drugs for renewal

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Does	Syrup/ Suspension/ Ellixir(Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot).
1	Anti-bacterial	300	20	30	20 15
2	Anti-fungal	300	20	30	15
3	Anti-viral	300	20	30	15
4	Anti-malarial	300		30	
5	Anti-tuberculous	300		30	
6	Anti-amoebic	300	20	30	20
7	Anthelmintic				

	(a)Single dose	50	20		
	(b)Multiple doses	50	20		
8.	Anti-inflammatory Drugs(Non-steroidal)	300	20	30	15
9	Anti-depressant	300	20	30	
10	Anti-psychotic	300	20	30	
11	Anti-convulsant	300	20	30	
12	Anti-parkinsonism	300	20	30	
13	Anxiolytic	300	20	30	
14	Anti-diabetic	300		30	
15	Anti-thyroid	300			
16	Anti-emetic	300	20	30	
17	Anti-diarrhoeal	300	20		
18	Antispasmodic	300	20	30	
19	Antacid	300	20		
20	Anti-ulcer	300	20	30	
21	Anti-asthmatic	300	20	30	
22.	Antitussive	300	20		
23.	Antihistamine	300	20	30	
24.	Mucolytic	300	20		
25.	Anti-anginal	300		30	
26.	Anti-hypertensive	300		30	
27.	Anti-arrhythmic	300		30	
28.	Beta adrenergic Blockers	300		30	

29.	Calcium Antagonist	300		30	
30.	Diuretic	300		30	
31.	Anti-hyperlipidaemic	300			
32.	Anti-heamorrhoidal	300			
33.	Ant-neoplastic	100		10	

*Antineoplastic from India must be submitted with own COA and Lab analysis Report form SGS India Pvt. Ltd., (India)

*Antineoplastic from other Countries must be submitted with own COA and Test result from accreditated Laboratory.

No	Drug Category	Required Quantities			
		Tablets/ Capsules/ United Does	Syrup/ Suspension/ Ellixir(Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.)
34.	Anti-migraine	300	20	30	
35.	Anaesthetics*			30	20
36.	Amino Acids	300	10(LVP)20	15 (SVP)	
37.	Antianaemic	300	20	50	
38.	Cold Remedy	300	20		
39.	Contraceptive	30cycles			
40.	Corticosteroids	300	30		
41.	Intravenous Replacement Fluids			10 (LVP) 20	

				(SVP)
42.	Multivitamin	300	20	50
43.	Nootropic	300	20	30
44.	(a)Oral Rehydration Salt tablets	100		
	(b)Oral Rahydration Salt Powder	30	Sachets (1 L pack) 50 Sachets (<one L pack)	
45.	Uricosurics	300		
46.	*Vaccines			30
47.	Dermatologicals			15
48.	Eye/Ear Drops			15

LVP= Large Volume Parenteral, SVP=Small Volume Parenteral.

(500ml & above) (Less than 500 ml)

Note: (1) All the submitted sample drug must have a minimum one year of shelf-life .

(2) In case of large sized packs (e.g. 500's, 1000's liter pack or jar)the required amounts are 2bottles or boxes.

(3) If more than one type of packing or pack sizes are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remains have to be submitted in a minimum of one unit-pack.

Annex V

MODEAL CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Certificate of a Pharmaceutical Product'

This certificate conforms to the format recommended by the WHO (general instructions and explanatory notes attached)

Certificate No: _____

Exporting (Certifying) country : _____

Importing (Requesting) country : _____

1. Name and dosage form of product:

_____

1.1 Active ingredient(s)[2] and amount (s)[3] per unit dose:

_____

_____

_____

For complete qualitative composition including, see attached[4].

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5]

☐ Yes No ☐

1.3 Is the product actually on the market in the exporting country?

☐ Yes No ☐ Unknown ☐

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B[6].

2A.1 Number of product license[7] and date of issue:

_____

2A.2 Product license holder (name and address):

Name : _____

Address: _____

2A.3 Status of product-license holder:[8]

☐ a ☐ b ☐ c

2A.3.1For categories b and c the name and address of the manufacturer producing the dosage form are:9

Name : _____

Address: _____

2A.4 Is Summary Basis of Approval appended?[10]

☐ Yes ☐ No

2A.5 Is the attached, officially approved product information completer and consonant with the license?[11]

☐ Yes ☐ No ☐ Not provided

2A.6 Application for the certificate (name and address):[12]

Name : ----------

Address : ----------

2B.1 Application for the certificate (name and address):[12]

Name : ----------

Address : ----------

2B.2 Status of applicant:[8]

☐ a ☐ b ☐ c

2B.2.1For categories b and c, the name and of the manufacturer producing the dosage form is:[9]

Name : ----------

Address : ----------

2B.3 Why is marketing authorization lacking?

☐ not required ☐ under consideration

☐ not requested ☐ refused

2B.4 Remarks:[13]

---

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is producted?[9]

☐Yes ☐ No ☐ N/A

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspection(years): _____

3.2 Has the manufacture of this type of dosage from been inspected?

☐Yes ☐ No

3.3 Does the facilities and operations conform to GMP as recommended by the WHO?[5]

4. Does the information submitted by the applicant satiafy the certifying authority on all aspects of the manufacture of the product? [16]

If no explain : ----------

Address of the certifying authority :

Telephone number : ----------

Name of authorized person :

Signature of authorized person :

Stamp and date:

---

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing

arrangements and approved information for different dosage forms and different strengths can vary.

2. Use whenever possible, international Non-proprietary Names (INNs) or national non-proprietary names.
3. The formula (complete composition) of dosage form should be give on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product license holder.
5. When applicable, append details of any restriction applied to the sale, distribution or asministration of the product that is specified in the product license.
6. Section 2A and 2B are mutually exclusive.
7. Indicate when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and/ or labels a dosage form manufactured by a independent company; or
   (c) is involved in non of the above
9. This information can be provided only with the consent of the product license holder or, in the case of non registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

   It should be noted that information concerning the site of production is part of the product license.

If the production site is changed, the license must be updated or it will cease to be valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11. This refers to the product information approved by the competent national regulatory authority such as a Summary of product Characteristics (SmPC).

12. In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to the authority by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration:

    (a) the product has been developed exclusively for the treatment of conditions-particularly tropical diseases-not endemic in the country of export;

    (b) the product has been reformulated with a view to improving its stability under tropical conditions;

    (c) the product has been reformulate to exclude excipients not approved for used in pharmaceutical products in the country of import;

    (d) the product has been reformulated to meet a different maximum dosage limited for an active ingredient;

    (e) any reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report

of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Service No.823, 1992 Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No.822, 1992 Annex 1)

16. This section is to be completed when the product license or applicant conforms to status (b) or (c) as described in not 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over of these parties.

Annex-VI

PROFORMA STATEMENT

SN	TRADE NAME	GENERFIC NAME OR FORMULA	INDICATION	REMARKS

PACKING :

SHELF LIFE :

FOR PRICE :

MANUFACTURER :

Annex-VII

Department of Food and Administration

Summary Drug Information

	Name	Address	Phone/ Fax
Applicant*			
Owner of Drug			
Manufacturer			

For Official Use
Date of Application
Application No:
Assessment Fees:
Registration Certificate No:
Date of issue:
Date of expiry:
Sales Category:
Variation:

Brand Name
Non Proprietary Name
Dosage Form
Strength
Therapeutic
Presentation** (type of packing, Pack siz~)

Indications:
Dosage:

Composition (including excipients & coloring substances)

*An authorized representative of owner of drug in Myanmar

*All type of packagings that are applied for registration have to be stated.

DRUG SAMPLE	
Batch No. Manufacture Date Exp. Date Certificate of Analysis	Type of Packing Presentation(Pack Size) Submitted Quality

Finished Product Specifications	
Physical Specifications (colour,shape, size, weight, hardness, disintegration etc.)	Chemical & Microbiological specifications

Packing Specifications(primary packaging, secondary packaging)

Shelf life & recommended Storage conditions

*Submission for consideration	*Approval/ Rejection

*For official Use

Steps to be taken in submitting dossier and sample drugs for Registration

The following are the steps which if an applicant follows strictly will take him straight to the finishing line.

Steps	Applicant	Steps	FDA
1.	A thorough study of a booklet " A Guideline of Submission of Application for Drug Registration".		
2.	Getting Form(1), a prescribed form for application. (Separate Forms(1) are to be used for application of different king of drugs and dosage forms). Form (1) is available at General Affairs Section.		
3.	Entering list of drugs, wished to be applied for registration, in register book at Drug Control Section.		
4.	Getting a letter of intimation from DFDA to remit required assessment fees. Remitting required payment to MD account of DFDA.	1.	Issuing letter of intimation for remittance of assessment fees.
5.	Submission of Sample drugs. a) Getting DFDA approval for importation of sample drugs. a.1 The following shall be submitted to Drug Control section. When ask for approval - issued by MEB upon remittance of assessment fees + a letter, in a format prescribed by DFDA, informing DFDA -List of sample drugs to be imported, specifying name of drug (trade name, generic name), dosage form, presentations, contents of each unit dose, pack size (accounting unit), quantities. (For the convenience sake, a form has been prepared by DFDA, which just needs to be filled out).	2. 3.	Checking the documents: returning an original copy after checking.(DCS 1) Issuing an approval for importation of sample drugs(DCSI)

Steps	Applicant	Steps	FDA
	- For the sample drugs which are already port, in addition to above, airway bill, singed invoice, & packing list of sample drugs. a.2 For the sample drugs which are shipped prior to * step 4, (formal application of registration) approval of importation will not be issued. a.3 Compliance with Trade and Custom* department's regulations on import is absolutely necessary. b) Submission of sample drugs within one week from the date of clearance from port of entry. b.1 The submitted samples must be accompanied with and original approval issued by DFDA, Photocopied airway bill, signed invoice and packing list of sample drugs and original COA.	4.	Accepting the sample drugs; issuing the receipt of sample drugs.
6.	Submission of Form (1) and registration dossier at drug control section for checking against check-list. a) For non-conforming dossier, Submission to DAC for Rejection. b) For conforming dossier getting an acknowledgement of receipt of Form (1) and registration dossier from Drug Control Section.	5.	Checking against check-list for documentary requirements for drug registration. - Accepting conforming dossier b.1.Issuing acknowledgement of receipt of Form (1) and registration dossier. b.2. Designating application number and date for future reference.
7.	Getting an intimation (4 months from step 6(b) to provide further information, if it is needed. a) Submitting further information at Dispatch Section.	6.	Previewing of documents a) Proceeding to further stages of evaluation if the information provided is adequate.
Steps	**Applicant**	**Steps**	**FDA**
			b) Asking further information if the information provided is inadequate.
8.	Enquiring about approval approximately 1 year after **step 7** for common, established drugs, approximately 1 ½ year or more for New product in Myanmar.		
9.	For approved drugs:	7.	Issuing letter of intimation to remit

	a) Getting letter of intimation form General Affairs Section (GAS), to remit registration fees to DFDA MD. Account b) Remitting registration fees within 90 days from the date of intimation.		registration fees for those which are approved. (General Affairs Section, GAS)
10.	For rejected drugs.	8.	Issuing letter of intimation for rejected products. (GAS)
11.	Submission of Credit Advice issued by DFDA upon remittance of registration fees. One original and two photocopies of credit advice have to be submitted in a forwarding letter in FDA prescribed format, at General Affairs Section.	9.	Accepting and acknowledging the receipt of Credit Advice.
12	Getting Registration Certificate one month after step 11.	10.	Issuing Registration Certificate two weeks to one month after receiving Credit Advice. (GAS) The Registration Certificate will be handed only to an authorized representative of owner of drug, If it is a local company, the person shall be an employee of the company (contact
Steps	**Applicant**	**Steps**	**FDA**
			person) whose specimen signatures have been provided to FDA by the company.