UNION OF MYANMAR

Ministry of Health

Department of Health

Food and Drug Administration

A Guideline on Drug Registration Application

(revised in Feb, 2009)

UNION OF MYANMAR
Ministry of Health
Department of Health
Food and Drug Administration
35, Min Kyaung Street, Dagon Township, Yangon, Myanmar.
(Phone. 95 - 1 - 245332)

Ref : DAC / RM / 213 / 09

Date - 24th February, 2009

Initial application for Registration

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

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. 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). 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 authorised representative of owner of drug. * Any application made by mail or fascimile or means other than in person, will not be accepted. An authorised representative has to be a resident in Myanmar.
   (b) Should an authorisation for representation be granted to the local company, the representative shall be a company employee authorised to serve as a contact person.

7. Registration assessment fees must have been remitted to Myanmar Foreign Trade Bank (MFTB) in favour of Drug Advisory Committee Account No. (IDA-06-91892) when submission of the application form is made.

* Product licence holder at country of origin

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 the approval but also with the regulations of Commerce and Customs Department.

(b) As 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 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.

- Drug samples the quantity of which is sufficient for clinical trial on sixty patients. For certain rare diseases fewer numbers of samples may be acceptable.
- Samples for laboratory analysis
- Samples for retention.

(b) For the total numbers of sample drugs to be submitted, please refer to FDA circular 1/97 (a) " 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 of drug samples.

11. (a) When the drug is approved for registration, the applicant will be notified to remit 200 United States dollar as Registration Fees. The notification will be made only on the notice board of FDA.

(b) **Failure to remit Registration Fees within 90 days 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 MFTB 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 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 Registration Certificate of drug.

4. (a) When it is decided to approve of changes, US$ 100 (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 90 days before the validity of the registration terminates. Failure to adhere to the 90 days 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. However if the situation warrants the repeat-clinical trial, the samples will be asked. The samples for laboratory analysis and for retention are still required. Please refer to FDA circular 1/97 b" 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 the Drug Advisory Committee Account No.IDA-06-91892 at the time of application of renewal of registration. When the renewal of registration is approved of, two hundred United States dollar must be remitted as Registration Fees.

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

7. Failure to apply for renewal of registration shall result in invalidation of registration with effect from the date of expiry of the certificate.

Fees levied

1. Registration Assessment Fees 100 US$ + Fees (in Kyats) for Laboratory analysis
2. Registration Fees 200 US$
3. Variation of Registration 100 US$ for each variation

Note: (1) & (2) are levied either for 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 authorised to be sold in country of origin.

2. (a) Properly endorsed photocopy of valid manufacturing licence.
   (b) GMP certificate of manufacturing plant.

3. A letter of authorisation 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. Quality 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		Amounts
(a)	Assessment fees	US$ 100 + Fees in Kyats for laboratory analysis
(b)	Registration fees	US$ 200
(c)	Variation fees	US$ 100

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

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

THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

PART 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) GMP certificate of contract manufacturer

3.2 For manufacturing " under- license " (country specific)
- (a) License of pharmaceutical industries
- (b) GMP certificate of manufacturer
- (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 Unit 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 its 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 : " Tablet 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 medicinal products and other froms 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

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 storage
- (e) Nature and contents of container

5.2.7 Marketing Authorization Holder
5.2.8 Marketing Authorization Numbers
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 cell substrate
- Cell banking system, characterization and testing.
- Viral safety evaluation.

S2.4 Controls 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 the process. *
- Stability data supporting storage conditions. *

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

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 manufacturer

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 procedures used for testing of drug substance.
- Compendial methods or appropriate information from the manufacturer.

S4.3 Validation of 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 usd for testing of the drug substance. *
- Compendial reference standards

S6 Container Closure System *
- Descriptions of the container closure systems.

S7 Stability
- Stability report. *
- Literature data

P **DRUG PRODUCT**

P1 Description and Composition

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

Composition
- Name quantity 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 form, Formulation, Manufacturing process, container closer system .

P2.2 Components of the Drug Product

P2.2.1 Active ingredient
- Justification of the compatibility of the active ingredient with excipients Lised in P1 In case of combination products, justification of the compatibility of active ingredients with each other. *
- Literature data.

P2.2.2 Excipients *
- Justification of the choice of excipients used in P1. which may influence the drug product performance.

P2.3 Finished Product

P2.3.1 Formulation 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 optimisation 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 diluent(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 manufacturer.

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 compendial method applicability – precision & accuracy.

P5.4 Batch Analyses
- Description and test results of all relevant batches.

P5.5 Characterisation of Impurities
- Information on the characterisation of impurities. *
- Compendial requirements or appropriate information from 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 Vivo
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
1.2.1 Absorption
1.2.2 Distribution
1.2.3 Metabolism
1.2.4 Excretion
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 and 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:
  - 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 safelty & efficacy are well known, have the same route of administration & strength & the same or similar indication as in those countries.

Annex II

ကျန်းမာရေးဝန်ကြီးဌာန
Ministry of Health
ကျန်းမာရေးဦးစီးဌာန
Department of Health
အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာန
Food and Drug Adminstration

ထောက်ခံချက်အမှတ် ————————
Approval No.

သက်ဆိုင်ရာသို့
To whom it may concern

အောက်ဖော်ပြပါပုဂ္ဂိုလ်သည် ဖော်ပြပါဆေးဝါးများအား မြန်မာနိုင်ငံတွင် မှတ်ပုံတင်ရန် လျှောက်ထားလာပါသဖြင့် လိုအပ်သော စမ်းသပ်မှုများဆောင်ရွက်ရန် ကျောဘက်တွင် ဖော်ပြထားသည့်ဆေးဝါးနမူနာများကို မြန်မာနိုင်ငံအတွင်းသို့ တစ်ကြိမ် တင်သွင်းခြင်းအား ထောက်ခံလိုက်သည်။

In order to carry out necessary tests on drugs which have been applied for registeration 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	
နိုင်ငံသားစိစစ်ရေးကဒ်ပြားအမှတ်	.....
NRC. No .	
လိပ်စာ	.....
Address	
လုပ်ငန်းအမည်	.....
Name of Business	
တင်ပို့သူအမည်	.....
Name of Consignor	
လိပ်စာ	.....
Address	
ခွင့်ပြုသည့်နေ့	.....
Date of Approval	
ခွင့်ပြုသည့်ကာလ	.....
Valid up to	

ဓါတ်ပုံ

လက်မှတ် .....
Signature .....
ခွင့်ပြုသူအမည်.....
Name .....
ရာထူး .....
Designation .....

စည်းကမ်းချက်များ ပူးတွဲတွင်ကြည့်ပါ
See conditions attached

ထောက်ခံသည့်ဆေးဝါး

Approved Drugs

စဉ် Sr. No	ဆေးဝါးအမည် (အမှတ်တံဆိပ်အမည်/မျိုးရိုးအမည်) Name of Drug (trade name/generic name)	ဆေးဝါးပုံသဏ္ဌာန်/ ပါဝင်မှုပမာဏ Dosage forms/ Strength	ထုပ်ပိုးပုံ Packing & Presentation	ရေတွက်ပုံ A/U	ထောက်ခံသည့်ပမာဏ Approved Amount	ထုပ်လုပ်စက်ရုံ/နိုင်ငံ Name of Manufacturer/ Country

(အကောက်ခွန်ဌာနမှ ဖြည့်စွက်ရန်)

ထုတ်ပေးသူလက်မှတ် .....

ထုတ်ပေးသူအမည် .....

ထုတ်ပေးသူရာထူး/ဌာန .....

စည်းကမ်းချက်များ
Conditions

၁။ ဤတင်သွင်းခြင်းထောက်ခံချက်(မူရင်း)သာ တရားဝင်ဖြစ်သည်။ မည်သည့်ပုံစံမျိုးဖြင့်ဖြစ်စေ၊ မိတ္တူသည် တရားဝင်ထောက်ခံချက် မဟုတ်

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

၂။ ဤဆေးဝါးနမူနာ တင်သွင်းခြင်းထောက်ခံချက်သည် တစ်ကြိမ် တင်သွင်းခြင်းကို ထောက်ခံခြင်း ဖြစ်ပြီး ဖော်ပြထားသော သတ်မှတ်ကာလအတွင်းတွင်သာ အကျိုးသက်ရောက်စေရမည်။

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

၃။ ဤတင်သွင်းခြင်းထောက်ခံချက်သည်လက်မှတ်တွင် ဖော်ပြထားသည့်ပုဂ္ဂိုလ်အာ ခွင့်ပြုခြင်းသာ ဖြစ်ပြီး အခြားတစ်ဦး တစ်ယောက်အား လွှဲပြောင်းခြင်း မပြုရ။

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

၄။ အသုံးမပြုသည့် တင်သွင်းခြင်း ထောက်ခံစာအား တင်သွင်းခွင့် သက်တမ်းကုန်သည့်နေ့မှစ၍ (၂)ရက် အတွင်း အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာနသို့ ပြန်လည်အပ်နှံရမည်။

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

၅။ တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲယေးပါ ဖော်ပြထားသော အချက်အလက်များအား ပြင်ဆင်ခြင်း၊ ဖျောက်ဖျက်ခြင်း၊ မပြုလုပ်ရ။

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

၆။ ဤတင်သွင်းခြင်းထောက်ခံစာအရ တင်သွင်းခဲ့သော ဆေးဝါးနမူနာများနှင့် တင်သွင်းခွင့်ထောက်ခံစာအား အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာနသို့ ဆိုက်ရောက်ရာ ဌာနမှ ထုတ်ယူပြီးသည့်နေ့မှစ၍ (၂)ရက် အတွင်းပေးပို့ရမည်။

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

၇။ ပေးပို့သည့် ဆေးဝါးနမူနာသည် တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲယေးပါ သတ်မှတ်ချက်များအတိုင်း ဖြစ်စေရမည်။ ကွဲလွဲချက်များဖြစ်ပေါ်ပါက တင်သွင်းခွင့်ရရှိသူမှ လုံးဝ တာဝန်ယူရမည်။

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

၈။ အထက်ပါ စည်းကမ်းချက်များအား လိုက်နာဂရုန် မှက်ကွက်ပါက တည်ဆဲဥပဒေများအရ အရေးယူခြင်း ခံရမည်။

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

၉။ ဤတင်သွင်းခြင်းထောက်ခံစာကိုင်ဆောင်သူသည် မှတ်ပုံတင်လျှောက်ထားရန်အတွက် ဆေးဝါးများ တင်သွင်းရာတွင် တည်ဆဲအကောက်ခွန်စည်းမျဉ်းစည်းကမ်းလုပ်ထုံးလုပ်နည်းများကို လိုက်နာရမည်။

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

Annex III

DEPARTMENT OF HEALTH
FOOD & DRUG ADMINISTRATION

Required quantities of sample drugs for initial registration

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/ Suspension/ Elixir (Up to 120 ml)	Injection (Ampoules / Vials)	(Bot.)	Topical (Tubes/ Bot.)
1	Anti-bacterial	2500	100	350	350	100
2	Anti-fungal	2000		350		100
3	Anti-viral	2000				100
4	Anti-malarial	2000		350		
5	Anti-tuberculous	3000		350		
6	Anti-amoebic	2000	100	350	350	
7	Anthelmintic					
	(a) Single dose	150 doses	100			
	(b) Multiple dose	500 doses	100			
8	Anti-inflammatory Drugs(Non-steroidal)	2000	100	300		100
9	Anti-depressant	3000		300		
10	Anti-psychotic	3000		300		
11	Anti-convulsant	2000	100	350		
12	Anti-parkinsonism	4000				
13	Anxiolytic	2000		300		
14	Anti-diabetic	2000		250		
15	Anti-thyroid	5000				
16	Anti-emetic	2000	100	300		
17	Anti-diarrhoeal	2000				
18	Antispasmodic	2000		150		
19	Antacid	2000	100			
20	Anti-ulcer	2000	100	300		
21	Anti-asthmatic	2000	100	300		
22	Antitussive	2000	100			
23	Antihistamine	2000	100	350		100
24	Mucolytic	2000	100			
25	Anti-anginal	2000		350		
26	Anti-hypertensive	2000		300		
27	Anti-arrhythmic	2000		300		
28	Beta adrenergic blockers	2000		300		
29	Calcium Antagonnist	2000		300		
30	Diuretic	2000		200		
31	Anti-hyperlipidaemic	4000				
32	Anti-heamorrhoidal	2000				
33*	Anti-neoplastic					
34	Anti-migraine	2000				
35	Anaesthetics*					

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/ Suspension/ Elixir (Up to 120 ml)	Injection (Ampoules/ Vials)	(Bot.)	Topical (Tubes/ Bot.)
36	Amino Acids	2000			100 (LVP) 350 (SVP)	
37	Antianaemic	2000		350		
38	Cold Remedy	2000	100			
39	Contraceptive	200 cycles				
40	Corticosteroids	3000		350		100
41	Intravenous Replacement Fluids				100 (LVP) 350 (SVP)	
42	Plasma Expander				100	
43	I/V Glucose (10% 25% 50%)			350		
44	Multivitamin	2000	100	350		
45	Nootropics	3000		450		
46	(a)Oral Rehydration Salt tablets	700				
	(b)Oral Rahydration Salt Powder	200 Sachets (one liter pack) 400 Sachets (less than one liter pack)				
47	Uricosurics	2000				
48*	Vaccines					
49	Dermatologicals					100
50	Eye / Ear Drops					100

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

Note: (1) For those with (*) markings and for controlled medicine please check with FDA for exact number

(2) All the submitted sample drug must have a minimum of two years' shelf – life (or ¾ of * total shelf life)

(3) In case of large sized packs (e.g. 500's, 1000's, litre pack or jar) the required amounts are 7 bottles or boxes for 500 sized packs 1 litre pack & 5 bottles or boxes for 1000sized packs and packs which are more than 1 litre or 1kg sizes.

(4) 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 four unit-pack each if it is a small sized pack and two unit-pack each if it is a large sized pack.

Annex IV

DEPARTMENT OF HEALTH
FOOD & DRUG ADMINISTRATION
Circular No. 1/97 b
Required quantities of sample drugs for renewal

No.	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/ Suspension Elixir (Up to 120 ml)	Injection (Ampoules/ Vials)	Bot.	Topical (Tubes/ Bot.)
1.	Anti-bacterial	500	20	50	20	15
2.	Anti-fungal	500	20	50		15
3.	Anti-viral	500	20	50		15
4.	Anti-malarial	500		50		
5.	Anti-tuberculous	500		50		
6.	Anti-amoebic	500	20	50	20	
7.	Anthelmintic					
	(a) Single dose	50	20			
	(b) Multiple does	50	20			
8.	Anti-inflammatory Drugs (Non-steroidol)	500	20	50		15
9.	Anti-depressant	500	20	50		
10.	Anti-psychotic	500	20	50		
11.	Anti-convulsant	500	20	50		
12.	Anti-parkinsonism	500	20	50		
13.	Anxiolytic	500	20	50		
14.	Anti-diabetic	500		50		
15.	Anti-thyroid	500				
16.	Anti-emetic	500	20	50		
17.	Anti-diarrhoeal	500	20			
18.	Antispasmodic	500	20	50		
19.	Antacid	500	20			
20.	Anti-ulcer	500	20	50		
21.	Anti-asthmatic	500	20	50		
22.	Antitussive	500	20			
23.	Anti-histamine	500	20	50		
24.	Mucolytic	500	20			
25.	Anti-anginal	500		50		
26.	Anti-hypertensive	500		50		
27.	Anti-arrhythmic	500		50		
28.	Beta adrenergic blockers	500		50		
29.	Calcium Antagonist	500		50		
30.	Diuretic	500		50		
31.	Anti-hyperlipidaemic	500				
32.	Anti-haemorrhoidal	500				
33*.	Anti-neoplastic					

No.	Drug Category	Requireed Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/ Suspension Elixir (Up to 120 ml)	Injection (Ampoules/ Vials)	Bot.	Topical (Tubes/ Bot.)
34.	Anti-migraine	500	20	50		
35*.	Anaesthetics					
36.	Amino Acids	500			10(LVP) 50(LVP)	15
37.	Antianaemic	500	20	50		
38.	Cold Remedy	500	20			
39.	Contraceptive	50 cycles				
40.	Corticosteroids	500		50		
41.	Intravenous Replacement Fluids				10 (LVP) 50 (SVP)	
42.	Multivitamin	500	20	50		
43.	Nootropics	500	20	50		
44.	(a) Oral Rehydration Salt tables	100				
	(b) Oral Rehydration Salt Powder	30 Sachets (1 L pack) 50 Sachets (< 1L pack)				
45.	Uricosurics	500				
46.	* Vaccines					
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) For those with(*) markings and for controlled medicine please check with FDA for exact number.

(2) All the submitted sample drugs must have a minimum of **two years'** shelf – life

(3) In case of large sized packs(e.g 500's, 1000's litre pack or jar) the required amounts are 3 bottles & 2 bottles or boxes for 1000 sized packs and packs which are more than 1 litre or 1 kg sizes.

(4) 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 four unit-pack each if it is a small sized pack and two unit-pack each if it is a large sized pack.

MODEL CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Certificate of a Pharmaceutical Product[1]

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 excipients, see attached[4],

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

❑ Yes ❑ No

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].

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

_____

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

Name :_____

Address :_____

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

☐ a ☐ b ☐ c

2A.3 1 For 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 complete and consonant with the licence?[11]

☐ Yes ☐ No ☐ Not provided

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

Name :_____

Address :_____

2B.1 Applicant for certificate (name and address):

Name :_____

Address :_____

2B.2 Status of applicant:[8]

☐ a ☐ b ☐ c

2B.2.1 For categories b and c, the name and address 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 product?[14]

☐ 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 form been inspected?

☐ Yes ☐ No

3.3 Does the facilities and operations conform to GMP as recommended by the WHO?[15]

☐ Yes ☐ No ☐ N/A

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

If no explain: _____

Address of the certifying authority:

_____

Telephone number:

Fax 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 given on the certificate or be appended.

4. Details of quantitative composition are preferred, but their provision is subject to the aggreement of the product licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Sections 2A and 2B are mutually exclusive.

7. indicate when applicable, if the licence 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 an independent company; or
   (c) is involved in non of the above

9. This information can be provided only with the consent of the product licence 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 licence. If the production site is changed, the licence 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 licence 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 reformulated to exclude excipients not approved for used in pharma ceutical products in the country of import:
   (d)the product has been reformulaed to meet a different maximum dosage limit 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 Specifica--tions for Pharmaceutical Preparations (WHO Technical Report Series 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 licence holder or applicant conforms to status (b) or (c) as described in note 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 each of these parties.

Annex - VI

PROFORMA STATEMENT

SN	TRADE NAME	GENERIC NAME OR FORMULA	INDICATION	REMARKS

PACKING :
LIFE :
FOB PRICE :
MANUFACTURER :

Annex-VII

Department of Health
Food and Drug 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	Composition (including excipients & coloring substances)
Non Proprietary Name	
Dosage Form	
Strength	
Therapeutic Category	
Presentation** (type of packing, pack size)	

Indications:
Dosage:

* An authorised representative of owner of drug in Myanmar

* All types 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

Packaging 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 Guidline on 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 kind 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 (1).		
4.	Getting a letter of intimation from FDA to remit required assessment fees. Remitting required payment to account No.IDA-06-91892 at Myanmar Foreign Trade Bank. Payment made either by cash or FEC or by telegraphic transfer usually helps avoid unwanted delay in obtaining credit advice issued by MFTB for the payment.	1.	Issuing letter of intimation for remittance of assessment fees. (Drug Control Section 1 DCS 1).
5.	Submission of Sample drugs. a) Getting FDA approval for importation of sample drugs. a.1. The following shall be submitted to Drug Control section I. when ask for approval • one original and two photocopies of Credit Advice issued by MFTB upon remittance of assessment fees + a letter, in a format prescribed by FDA, informing FDA that payment for the drugs has been made.	2.	Checking the documents; returning an original copy after checking. (DCS 1)

Steps	Applicant	Steps	FDA
	• 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 FDA, which just needs to be filled out). • for the sample drugs which are already at port, in addition to above, airway bill, signed 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 Commerce and Custom department's regulations on import is absolutely necessary. b) Submission of sample drugs within two days from the date of clearance from port of entry. b.1. The submitted samples must be accompanied with an original approval issued by FDA, photocopied airway bill, signed invoice and packing list of sample drugs.	3.	Issuing an approval for importation of sample drugs (DCS 1)
		4.	Accepting the sample drugs; issuing the receipt of sample drugs.
6.	Submission of Form (1) and registration dossier at drug control section (1) for checking against check-list. Getting the result of checking the same day. a) Retreating non-conforming dossier, correcting defects and getting back to step 6. b) For conforming dossiers getting an acknowledgement of receipt of Form (1) and registration dossier from Drug Control Section (1).	5.	Checking against check-list for documentary requirements for drug registration. a) Returning non-conforming dossier b) 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.

Steps	Applicant	Steps	FDA
		6.	Previewing of documents a) Proceeding to further stages of evaluation if the information provided is adequate. b) Asking further information if the information provided is inadequate. Proceeding to further stages of evaluation when the information asked for arrives.
7.	Getting an intimation (within 21 days from step 6(b)) to provide further information, if it is needed. a) Submitting further information at Dispatch Section.		
8.	Enquiring about approval approximately 6 months after step 6 for common, established drugs, approximately 9 months for less common drugs but not new chemical entity and approximately 12 months for new chemical entity (NCE).		
9.	For approved drugs: a) Getting letter of intimation from General Affairs Section (GAS), to remit registration fees at MFTB. b) Remitting registration fees within 90 days from the date of intimation (to avoid unwanted delay, remittance in Cash, FEC or by TT is advisable)	7.	Issuing letter of intimation to remit 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 MFTB 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.

Steps	Applicant	Steps	FDA
		6.	Previewing of documents a) Proceeding to further stages of evaluation if the information provided is adequate. b) Asking further information if the information provided is inadequate. Proceeding to further stages of evaluation when the information asked for arrives.
7.	Getting an intimation (within 21 days from step 6(b)) to provide further information, if it is needed. a) Submitting further information at Dispatch Section.		
8.	Enquiring about approval approximately 6 months after step 6 for common, established drugs, approximately 9 months for less common drugs but not new chemical entity and approximately 12 months for new chemical entity (NCE).		
9.	For approved drugs: a) Getting letter of intimation from General Affairs Section (GAS), to remit registration fees at MFTB. b) Remitting registration fees within 90 days from the date of intimation (to avoid unwanted delay, remittance in Cash, FEC or by TT is advisable)	7.	Issuing letter of intimation to remit 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 MFTB 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.

Steps	Applicant	Steps	FDA
12.	Getting Registration Certificate two weeks to one month after step 10.	10.	Issuing Registration Certificate two weeks to one month after receiving Credit Advice. (GAS) The Registration Certificate will be handed only to an authorised representative of owner of drug. If it is a local company, the person shall be an employee of the company (contact person) whose specimen signatures have been provided to FDA by the company.