ကျန်းမာရေးဝန်ကြီးဌာန

Ministry of Health

ကျန်းမာရေးဦးစီးဌာန

Department of Health

အစားအသောက်နှင့်ဆေးဝါးကွပ်ကဲရေးဌာန

Food and Drug Administration

ထောက်ခံချက်အမှတ် ----------

Approval No.

သက်ဆိုင်ရာသို့

To whom it may concern

အောက်ဖော်ပြပါပုဂ္ဂိုလ်သည် ဖော်ပြပါဆေးဝါးများအား မြန်မာနိုင်ငံတွင် မှတ်ပုံတင်ရန် လျှောက်ထားလာပါသဖြင့် လိုအပ်သော စမ်းသပ်မှုများဆောင်ရွက်ရန် ကျောဘက်တွင် ဖော်ပြထားသည့်ဆေးဝါးနမူနာများကို မြန်မာနိုင်ငံအတွင်းသို့ တစ်ကြိမ်တင်သွင်းခြင်းအား 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 improt one consignment of drug samples as specified in the attached schedule overleaf.

တင်သွင်းခွင့်ရရှိသူအမည် ----------
Name of Person

နိုင်ငံသားစီစစ်ရေးကဒ်ပြားအမှတ် ----------
NRC.No

လိပ်စာ ----------
Address

လုပ်ငန်းအမည် ----------
Name of Business

တင်ပို့သူအမည် ----------
Name of Consignor

လိပ်စာ ----------
Address

ခွင့်ပြုသည့်နေ့ ----------
Date of Approval

ခွင့်ပြုသည့်ကာလ ----------
Valid up to

မာတ်ပုံ

စည်းကမ်းချက်များ ပူးတွဲတွင်ကြည့်ပါ
See conditions attached

လက်မှတ် ----------
Signature ----------
ခွင့်ပြုသူအမည် ----------
Name ----------
ရာထူး ----------
Designation ----------

ထောက်ခံသည့်ဆေးဝါး
Approved Drugs

စဉ် Sr. No.	ဆေးဝါးအမည် (အမှတ်တံဆိပ်အမည်/မျိုးရိုးအမည်) Name of Drugs (trade name/generic name)	ဆေးဝါးပုံသဏ္ဌာန်/ ပါဝင်မှုပမာဏ Dosage forms/Strength	ထုတ်ပိုးပုံ 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။ မည်သည့်ပုံစံမျိုးဖြစ်စေ၊ မိတ္တူသည် တရားဝင်ထောက်ခံချက် မဟုတ်
This approval shall be official only use of original Approval Certificate. Copy in any from shall be void.

၂။ ဤဆေးဝါးနမူနာ တင်သွင်းခြင်းထောက်ခံချက်သည် တစ်ကြိမ်တင်သွင်းခြင်းကို ထောက်ခံခြင်းဖြစ်ပြီး ဖော်ပြထားသော သတ်မှတ်ကာလအတွင်းတွင်သာ အကျိုးသက်ရောက်စေရမည်။
This approval shall be applicable for only one consignment and shall be invalidated from the date stated on it.

၃။ ဤတင်သွင်းခြင်းထောက်ခံချက်သည် လက်မှတ်တွင် ဖော်ပြထားသည့်ပုဂ္ဂိုလ်အား ခွင့်ပြုခြင်းသာဖြစ်ပြီး အခြားတစ်ဦးတစ်ယောက်အား လွှဲပြောင်းခြင်းမပြုရ။
The Approval is granted to a person as stated in the permit. This permit is not transferable to another person.

၄။ အသုံးမပြုသည့် တင်သွင်းခြင်းထောက်ခံစာအား တင်သွင်းခွင့် သက်တမ်းကုန်သည့်နေ့မှစ၍ (၂)ရက်အတွင်း အစားအသောက်နှင့် ဆေးဝါးကွပ်ကဲရေးဌာနသို့ ပြန်လည်အပ်နှံရမည်။
The unused approval must be returned to the Food & Drug Administration within two days from date of expiry of the approval.

၅။ တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲဇယားပေါ်ပါ ဖော်ပြထားသော အချက်အလက်များအား ပြင်ဆင်ခြင်း၊ ဖျောက်ဖျက်ခြင်း၊ မပြုလုပ်ရ။
No Change or deletion shall bed made to any expression of the approval and of the attached schedule.

၆။ ဤတင်သွင်းထောက်ခံစာအရ တင်သွင်းခဲ့သော ဆေးဝါးနမူနာများနှင့် တင်သွင်းခွင့်ထောက်ခံစာအား အစားအသောက်နှင့် ဆေးဝါးကွပ်ကဲရေးဌာနသို့ ဆိုက်ရောက်ရာဌာနမှ ထုတ်ယူပြီးသည့်နေ့မှစ၍ (၂)ရက်အတွင်းပေးပို့ရမည်။
The imported drug samples and the approval must be submitted to the Food & Drug Administration withintwo days from the date of clearance from port of entry.

၇။ ပေးပို့သည့် ဆေးဝါးနမူနာသည် တင်သွင်းခြင်းထောက်ခံစာနှင့် ပူးတွဲဇယားပါ သတ်မှတ်ချက်များအတိုင်း ဖြစ်စေရမည်။ ကွဲလွဲချက်များဖြစ်ပေါ်ပါက တင်သွင်းခွင့်ရရှိသူမှ လုံးဝတာဝန်ယူရမည်။
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။ အထက်ပါစည်းကမ်းချက်များအား လိုက်နာရန်ပျက်ကွက်ပါက တည်ဆဲဥပဒေများအရ အရေးယူခြင်းခံရမည်။
Failure to comply with above mentioned conditions, is liable to actions in accordance with exist ing rules and regulation laws.

၉။ ဤတင်သွင်းခြင်းထောက်ခံစာကိုင်ဆောင်သူသည် မှတ်ပုံတင်လျှောက်ထားရန်အတွက် ဆေးဝါးများတင်သွင်းရာတွင် တည်ဆဲအကောက်ခွန်စည်းမျဉ်းစည်းကမ်း လုပ်ထုံးလုပ်နည်းများကို လိုက်နာရမည်။
In importing sample drugs, holder of the approval shall comply with existing rules and regulations of Commerce and Customs department.

Annex III

DEARTMENT OF HEALTH
FOOD & DRUG ADMINISTRATION
Circular No. 1/97 a
Required quantities of sample drugs for initial registration

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Sus pension/Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot.)	(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	300	350	
7.	Anthelmintic					
	(a) Single dose	150 doses	100			
	(b) Multiple dose	500 doses	100			
8.	Anti-indflammatory Drugs (Non-Steroidol)	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	350		
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 adenergic blockers	2000		300		
29.	Calcium Antagonnist	2000		300		
30.	Diuretic	2000		200		
31.	Anti-hyperlipidaemic	4000				
32.	Anti-haemorrhoidal	2000				
33.*	Anti-neoplastic					

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Sus pension/Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot.)	(Tubes/Bot.)
34.	Anti-migraine	2000				
35.	Anaesthetics*					
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.	Notropics	3000		450		
46.	(a) Oral RehydrationSalt tablets	700				
	(b) Oral Rahydration Salt Power	200 Sachets (One litre Pack) 400 Sachets (less than one liter pack)				
47.	Uricosurics	2000				
48.*	Vaccines					
49.	Dematologicals					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 drugs must have a minimum of two years' shelf - life (or $^{3}/_{4}$ 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 packs or 1 kg jars & 5 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 packagings or pack sizeds 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 minium 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

DEARTMENT OF HEALTH
FOOD & DRUG ADMINISTRATION
Circular No. 1/97 b
Required quantities of sample drugs for initial registration

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Sus pension/Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot.)	(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 dose	50	20			
8.	Anti-indflammatory 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.	Antihistamine	500	20	50		
24.	Mucolytic	500	20			
25.	Anti-anginal	500		50		
26.	Anti-hypertensive	500		50		
27.	Anti-arrhythmic	500		50		
28.	Beta adenergic blockers	500		50		
29.	Calcium Antagonnist	500		50		
30.	Diuretic	500		50		
31.	Anti-hyperlipidaemic	500				
32.	Anti-haemorrhoidal	500				
33.*	Anti-neoplastic					

No	Drug Category	Required Quantities				
		Tablets/ Capsules/ Unit Dose	Syrup/Sus pension/Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot.)	(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.	Notropics	500	20	50		
44.	(a) Oral RehydrationSalt tablets (b) Oral Rahydration Salt Power	100 30 Sachets (One litre Pack) 50 Sachets (less than one liter pack)				
45.	Uricosurics	500				
46.*	Vaccines					
47.	Dematologicals					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 packagings or pack sizeds 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 minium 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 authorizatin lacking?

not required under consideration

not required refused

2B.4 Remarks[13] :

_____

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is prudced ?

☐ Yes ☐ No ☐ N/A

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 :

_____

Explanatory notes

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 in formation 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 (comlete composition) of the dosage form should be given on the certificate or be appended.

4. Details of quanlitative composition are preferred, but their provision is subject to the agreement 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 product, the applicant. Non-completion of this section indicates that the party concerned has hot 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 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 stabiligy under tropical condition
   (c) the product has been reformulated to exclude excipients not approved for use in pharmaceuticalproducts in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active igredient;
   (e) any other 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 requiement for good practices in the manufacture and qualigy control of durgs referred to in the certifi -cate are those included in the thirty-second report of the Expert Committee on Specifications for Pharma -ceutical Preparations (WHO Technical Report Series, No.823, 1992, Annex 1). Recommendations specifi -cally applicable to biological products have been formulated by the WHO Expert Committed on Biological Standardization (WHO Technical Report Series, No.822, 1992, Annex 1).

16. This section is to be completed when the product-licene holder of 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 te extent and nature of any controls exercised over each of these parties.

Annex - VI

PROFORMA STATEMENT

SN	TRADE NAME	GENERIC NAME OR FORMAULA	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
Non Proprietary Name
Dosage Form
Strength
Therapeutic Category
Presentation** (type of packing, pack size)

Composition (including excipients & coloring substances)

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 submit

The following are the steps which if an a

Steps	Application
1.	A thorough study of a booklet" A Guidelin Submission of Application for Drug Registration".
2.	Getting Form (1), a prescribed form for applic (Separate Forms (1) are to be used for applicati different kind of drugs and dosage forms). Form available at General Affairs Section.
3.	Entering list of drugs, wished to be applie registration, in register book at Drug Control Sectio
4.	Getting a letter of intimation from FDA to remit re assessment fees. Remitting required payment to ac No.91892 at Myanmar Foreign Trade Bank. Pa made either by cash or FEC or by telegraphic tr usually helps avoid unwanted delay in obtaining advice issued by MFTB for the payment.
5.	Submission of Sample drugs. (a) Getting FDA approval for importation of s drugs. a.1 The following shall be submitted to Control section I. When ask for approval • one original and two photocopies of Advice issued by MFTB upon remittan assessment fees + a letter, in a f prescribed by FDA, informing FDA payment for the drugs has been made.

Steps	Application	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 form 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. 4.	Issuing an approval for importation of sample drugs (DCS 1) 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 acknowledge-ment 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	Application	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 3 months after step 6 for common, established drugs, approximately 6 months for less common drugs but not new chemical entity and approximately 12 month 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	Application Steps	Steps	FDA
12.	Getting Registration Certificate one week after step 10.	10.	Issuing registration Certificate one week 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 a person shall be an employee of the company (contact person) whose specimen signatures have been provided to FDA by a company.