



REPUBLIC OF THE PHILIPPINES  
DEPARTMENT OF HEALTH  
**BUREAU OF FOOD AND DRUGS**  
Filinvest Corporate City  
Alabang, Muntinlupa City

18 January 2002

BUREAU CIRCULAR  
No. 01 s. 2002

**SUBJECT: Notarized Application Forms for Product Registration**

Effective February 1, 2002, all **incoming applications** for pharmaceutical product registration (Initial, Renewal, Monitored Release, Monitored Release Extension, and Re-application) must include in their submission the prescribed and duly notarized application form (as shown in Annex A and B). The said form is a combination of the old application form and the Certification. The forms were combined in order that only one document will be notarized.

Those companies who want to avail of the immediate processing of their **pending applications for renewal registration** as provided in Bureau Circular 15 s. 2001, are required to follow and submit the Certification by Responsible Persons (as shown in Annex C), in addition to the other requirements specified in the said Bureau Circular. Companies are also required to submit copies of all approved change/s (per product) that is/are not yet reflected in the previously issued Certificate of Product Registration, such as:

1. Change of Manufacturing Site
2. Change of Importer/Distributor/Trader/Packer/Repacker
3. Change of Shelf-Life
4. Change of Brand Name
5. Change of Generic to Branded, vice versa
6. Change/Additional Pack Size
7. Additional Indication

This Order shall take effect immediately.

**(Sgd) WILLIAM D. TORRES, Ph.D.**  
Director

**ANNEX A**  
**FOR INCOMING INITIAL/MONITORED RELEASE/  
MONITORED RELEASE EXTENSION REGISTRATION**

\_\_\_\_\_  
WILLIAM D. TORRES, Ph.D  
Director  
Bureau of Food and Drugs  
Alabang, Muntinlupa City

Attention: PRODUCT SERVICES DIVISION  
Drug Section

Sir/Madam:

For BFAD-PAICS use only	
<b>RSN</b>	

In accordance with RA 3720 and other related issuance, we wish to apply for the ( )  
initial ( ) monitored release ( ) monitored release extension registration of our product:

Approved generic name(s)	
Brand Name	
Dosage Strength per unit	
Dosage Form	
Primary Packaging (Market or Commercial Presentation)	
Registration Number (if applicable)	
Suggested Retail Price (SRP)	

Enclosed are the documents stated in the Checklist of Requirements for Registration and representative samples of our product.

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the

total information available. We certify that we have examined the following statements and we attest to their accuracy.

1. The Current Good Manufacturing Practice Guidelines for Drugs is applied in full in the manufacture of this product.
2. The formulation per dosage form is in agreement with the master formula and with the batch manufacturing record forms.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing records.
4. Product covered by this declaration will not undergo any change in the formulation, dosage form, strength, therapeutic indication, manufacturer, manufacturing process, labeling or commercial presentation without prior approval of this Office.
5. Each batch of all starting materials is tested or certified (in an accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and fully complied with those specifications cited in the claimed reference official monograph before it is released for manufacturing purposes.
6. All batches of active pharmaceutical ingredient(s) (API) are obtained from the following source(s):

<b>API</b>	<b>Name and Address of API Manufacturer</b>	<b>Name and Address of Supplier</b>

7. No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
8. Each batch of the finished product is tested and certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and fully complied with the specifications cited in the claimed reference official monograph before it is released for sale.
9. The person releasing the product for sale is an authorized and/or qualified person.
10. The procedures for control of the finished product have been validated for this formulation. The assay method has been validated for accuracy, precision, specificity and linearity.

11. The market authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
12. The market authorization holder has a standard operating procedure for handling batch recalls of its products.
13. All the documentation referred to in this application is available for review during a GMP inspection.

**COMPANY PHARMACIST**

Signature \_\_\_\_\_  
 Name (print or type) \_\_\_\_\_  
 Position (print or type) \_\_\_\_\_  
 Date \_\_\_\_\_

**OWNER/GENERAL MANAGER**

Signature \_\_\_\_\_  
 Name (print or type) \_\_\_\_\_  
 Position (print or type) \_\_\_\_\_  
 Date \_\_\_\_\_

**ACKNOWLEDGEMENT**

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

Name	Residence Certificate	Date Issued	Place Issued
1.			
2.			

Known to me and to me known to be the same persons who execute the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed

WITNESS MY HAND AND SEAL on the date and place first above written

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 Series of \_\_\_\_\_

**ANNEX B  
FOR INCOMING RENEWAL REGISTRATION**

WILLIAM D. TORRES, Ph.D  
Director  
Bureau of Food and Drugs  
Alabang, Muntinlupa City

Attention: PRODUCT SERVICES DIVISION  
Drug Section

Sir/Madam:

In accordance with RA 3720 and other related issuance, we wish to apply for the ( ) renewal registration of our product:

Approved Generic name(s)	
Brand Name	
Dosage Strength per unit	
Dosage Form	
Primary Packaging (Market or Commercial Presentation)	
Lot Number/Expiry Data of Representative Sample	
Registration Number	
Expiry Date of the Certificate of Product Registration (CPR)	
Suggested Retail Price (SRP)	

Enclosed are the documents stated in the Checklist of Requirements for Registration and samples in commercial presentation take from the last production batch before the submission of this application.

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available. We certify that we have examined the following statements and we attest to their accuracy:

1. The Current Good Manufacturing Practice Guidelines for Drugs is applied in full in the manufacture of this product.
2. The formulation per dosage form is in agreement with the master formula and with the batch manufacturing record forms.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing records.

4. Product covered by this declaration will not undergo any change in the formulation, dosage form, strength, therapeutic indication, manufacturer, manufacturing process, labeling or commercial presentation without prior approval of this Office.
5. Each batch of all starting materials is tested or certified (in an accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and fully complied with those specifications cited in the claimed reference official monograph before it is released for manufacturing purposes.
6. All batches of active pharmaceutical ingredient(s) (API) are obtained from the following source(s):

<b>API</b>	<b>Name and Address of API Manufacturer</b>	<b>Name and Address of Supplier</b>

7. No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
8. Each batch of the finished product is tested and certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and fully complied with the specifications cited in the claimed reference official monograph before it is released for sale.
9. The person releasing the product for sale is an authorized and/or qualified person.
10. The procedures for control of the finished product have been validated for this formulation. The assay method has been validated for accuracy, precision, specificity and linearity.
11. The market authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
12. The market authorization holder has a standard operating procedure for handling batch recalls of its products.
13. All the documentation referred to in this application is available for review during a GMP inspection.

**COMPANY PHARMACIST**

Signature \_\_\_\_\_  
 Name (print or type) \_\_\_\_\_

Position (print or type) \_\_\_\_\_  
Date \_\_\_\_\_

**OWNER/GENERAL MANAGER**

Signature \_\_\_\_\_  
Name (print or type) \_\_\_\_\_  
Position (print or type) \_\_\_\_\_  
Date \_\_\_\_\_

**ACKNOWLEDGEMENT**

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

Name	Residence Certificate	Date Issued	Place Issued
1.			
2.			

Known to me and to me known to be the same persons who execute the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed

WITNESS MY HAND AND SEAL on the date and place first above written

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Book No. \_\_\_\_\_  
Series of \_\_\_\_\_

ANNEX C  
FOR PENDING RENEWAL REGISTRATION

CERTIFICATION BY RESPONSIBLE PERSONS IN THE APPLICANT COMPANY

We, the undersigned, certify that all the information in the accompanying documentation concerning an application for the renewal registration of:

Approved Generic name(s)	
Brand Name	
Dosage Strength per unit	
Dosage Form	
Primary Packaging (Market or Commercial Presentation)	
Lot Number/Expiry Data of Representative Sample	
Registration Number	
Expiry Date of the Certificate of Product Registration (CPR)	
Suggested Retail Price (SRP)	
Routing Slip Number (RSN)	

Is correct and true, and reflects the total information available. We further certify that we have examined the following statements and we attest to their accuracy.

1. The Current Good Manufacturing Practice Guidelines for Drugs is applied in full in the manufacture of this product.
2. The formula per dosage form is in agreement with the master formula and with the batch manufacturing record forms.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing records.
4. Products covered by this declaration has not undergone any change in the formulation, dosage form, strength, therapeutic indication, manufacturer, labeling or commercial presentation from the registered specifications without prior approval from this Office.
5. Each batch of all starting materials is tested or certified (in an accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and fully complied with those specifications cited in the claimed reference official monograph before it is released for manufacturing purposes.
6. All batches of active pharmaceutical ingredient(s) (API) are obtained from the following source(s):

API	Name and Address of API Manufacturer	Name and Address of Supplier



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7. No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
8. Each batch of the finished product is tested and certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and fully complied with the specifications cited in the claimed reference official monograph before it is released for sale.
9. The person releasing the product for sale is an authorized and/or qualified person.
10. The procedures for control of the finished product have been validated for this formulation. The assay method has been validated for accuracy, precision, specificity and linearity.
11. The market authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
12. The market authorization holder has a standard operating procedure for handling batch recalls of its products.
13. All the documentation referred to in this application is available for review during a GMP inspection.

Along with this certification are the following:

1. Samples in commercial presentation taken from the last production batch before the submission of this certification
2. Photocopy of Official Receipt
3. Current and Valid LTOs of Manufacturer, Importer, Trader, Distributor, Packer and Repacker.
4. BFAD-Approved changes/amendments

**COMPANY PHARMACIST**

Signature \_\_\_\_\_  
Name (print or type) \_\_\_\_\_  
Position (print or type) \_\_\_\_\_  
Date \_\_\_\_\_

**OWNER/GENERAL MANAGER**

Signature \_\_\_\_\_  
Name (print or type) \_\_\_\_\_  
Position (print or type) \_\_\_\_\_  
Date \_\_\_\_\_

**ACKNOWLEDGEMENT**

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

Name	Residence Certificate	Date Issued	Place Issued
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Known to me and to me known to be the same persons who execute the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed

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