



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

Filinvest Corporate City
Alabang, Muntinlupa City



MALAYA AT MALUSOG
NA PAMAYANAN

26 October 2001

BUREAU CIRCULAR
No. 15 s. 2001

**SUBJECT: GUIDELINES FOR THE IMMEDIATE PROCESSING
OF PENDING APPLICATIONS FOR RENEWAL
REGISTRATION OF PHARMACEUTICAL PRODUCTS**

In line with the directive of the Secretary of Health to speed up the processing of applications for the registration of pharmaceutical products in consonance with the State of the Nation Address of the President to ensure the availability of affordable medicines, the BFAD shall expedite the processing of all pending renewal applications for registration of pharmaceutical products.

All pending applications for renewal registration filed with the BFAD shall be eligible for the immediate issuance of a CPR under the following conditions:

1) Submission of a declaration per product under oath signed jointly by the company pharmacist/medical director and responsible officer/person certifying that the product has not undergone any change in the formulation, dosage form, strength, therapeutic indication, manufacturer, labeling or commercial presentation from currently registered specifications in the form and substance shown in Annex "A" hereof

2) Submission of samples taken from the production batch immediately preceding the date of release of CPR

3) Payment in full of renewal fees with copies of official receipts

4) Current and valid LTOs

To ensure the orderly implementation of this Circular, the companies concerned shall submit to PAICS a summary of all pending renewal applications with the corresponding RSN, date of submission, official receipts and other data to help facilitate the processing of renewal applications.

The CPR of pharmaceutical products found not to be in compliance with the intent and coverage of this Circular will be subject to immediate suspension, revocation or recall if and when warranted.

This Order shall take effect immediately.


WILLIAM D. TORRES, Ph.D.
Director

**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 of registration of :

Generic name(s)
Brand name.....
Dosage strength per unit.....
Dosage form.....
Applicant Company.....
Date of Filing of Application.....
Expiry Date of the Certificate of Product Registration.....
Routing Slip Number.....

is correct and true, and reflect 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 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 has not undergone any change in the formulation, dosage form, strength, therapeutic indication, manufacturer, labeling or commercial presentation from the registered specifications.
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 complies 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 & Address of API Manufacturer	Name & Address of Supplier

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 complies 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 certificate is available for review during a GMP inspection.

1. Signature.....
- Name (print or type).....
- Position in company (print or type)... (*Medical Director/Company Pharmacist*)...
- Date.....

2. Signature.....
Name (print or type).....
Position in company (print or type)... (*Owner/General Manager*).....
Date.....

ACKNOWLEDGMENT