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

MALAYA AT MALUSOG
NA PAMAYANAN

13 December 2004

BUREAU CIRCULAR
No. 20 s.2004

**To:** All Drug Establishments and Parties Concerned

**Subject:** Submission of Application for Registration in Accordance with the Asean Common Technical Document (ACTD) Format

In preparation for the full implementation of the ASEAN requirements on registration by 2008, applicants are encouraged to prepare and submit registration dossier in accordance with the Asean Common Technical Document (ACTD) Format. The ACTD Format shall refer to the organization of documents for submission. Attached for your reference as "Annex A" is the ACTD format.

By January 2005, BFAD shall begin accepting submissions in accordance with the ACTD format.

Likewise, all manufacturers are encouraged to adopt the ASEAN harmonized requirements into their activities starting 2005 particularly on stability studies and process validation. Full implementation of the ASEAN ACTD/ACTR shall be by end of December 2008.

This is issued for the guidance, information and compliance of all concerned

**Prof. LETICIA - BARBARA B. GUTIERREZ, M.S.**
Director

*"Smoking is Dangerous to your Health"*

[Annex A]

Organization of Registration Dossier in Accordance with the ACDT Format

**Part I Table of Contents, Administrative Data and Product Information**

- ☐ Section A: Introduction
- ☐ Section B
  - ☐ Application Form
  - ☐ Letter of Authorization
  - ☐ Certifications
  - ☐ Labeling
  - ☐ Product Information (Summary of Product Characteristics (SPC), Package Insert, (PI), Patient Information Leaflet (PIL)

**Part II Quality Document**

Section A Table of Contents
B Quality Overall Summary
C Body of Data
I. Drugs Substance
1. General information
2. Manufacture
3. Characterization
4. Control of Drug Substance
5. Reference Standards or materials
6. Container Closure system
7. Stability

II. Drug product
1. Description & Composition
2. Pharmaceutical Development
3. Manufacture
4. Control of Excipients
5. Control of Finished products
6. Reference Standards or materials
7. Container closure system
8. Product Stability
9. Product Interchangeability

**Part III Non-Clinical Documents**

Section A: Table of Contents
Section B: Non-clinical Overview
Section C: Non-clinical Written and Tabulated Summaries

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

Section D: Non-clinical Study Reports

1. Table of Contents
2. Pharmacology
3. Pharmacokinetics
4. Toxicology

**Part IV: Clinical Document**

Section A: Table of Contents
Section B: Clinical Overview
Section C: Clinical Summary

1) Summary of Biopharmaceutics and Associated Analytical Methods
2) Summary of Clinical Pharmacologic Studies
3) Summary of Clinical Efficacy
4) Summary of Clinical Safety
5) Synopses of Individual Studies.

Section D: Tabular Listing of all Clinical Studies
Section E: Clinical Study Reports
Section F: List of Key Literature References

For presentation of data, the following should be observed:

1. Text and tables should be prepared using margins that allow the document to be printed on either A4 or 8.5 x 11 paper.
2. The left-hand margin should be sufficiently large that information is not obscured by the method of binding.
3. Font and size, (Time New Roman, 12-point font), for text and table should be of a style and size that are large enough to be easily legible, even after photocopying.
4. Every page should be numbered, with the first page of each part designated as page 1.
5. Common Technical Acronyms and abbreviations should be defined the first time they are used in each part.

ANNEX A

(Date)

(Applicant Company )
( )
( )

## CERTIFICATE OF BRAND NAME CLEARANCE

To whom this may concern:

Clearance for the use of the proposed brand name for (drug / veterinary / medical device / diagnostic reagent) preparation hereun indicated is hereby GRANTED.

**(Brand Name) (Active Ingredient/s)**

This brand name clearance shall be effective for one (1) year starting from the date of this Certificate.

**(Sgd) LETICIA BARBARA B. GUTIERREZ, M.S.**
Director

Ref. No. _____
PhP _____
OR# _____
Date _____