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

MALAYA AT MALUSOG NA PAMAYANAN

22 February 2006

BUREAU CIRCULAR
No. 2006 - 005

TO: ALL CONCERNED

SUBJECT: **Guidelines for the Submission of Application for Automatic Renewal Registration of Pharmaceutical Products, Medical Devices , Prepackaged Food and Food Products, and Household Hazardous Substances**

To effectively and efficiently implement Administrative Order No. 2005-0030, subject of which is the Guidelines and Procedure for the Automatic Renewal of the Certificate of Product Registration (CPR) issued by the Bureau of Food and Drugs, all applicants are directed to comply with the new requirements and procedures related to the receiving and processing of application for automatic renewal registration, as follows:

I. GUIDELINES

A. Application for automatic renewal shall be filed within ninety (90) days before the expiration of the CPR.

B. Applicants for automatic renewal of CPR shall submit the necessary requirements provided in **Item II. Requirements** hereof.

C. A surcharge of 50% shall be imposed for applications filed within sixty (60) days **after** the expiration date of the CPR.

D. A CPR that has not been filed for renewal within the 60-day grace period **after** the expiration date shall be automatically considered as initial registration.

E. Applications with option of one (1) and three (3) years as per Section 2(b) of AO No. 2005-0030 shall apply only to products that will no longer be marketed for more than three (3) years due to slow movement and phase out, which reason shall be contained in the application letter.

F. Applications with deficiencies, such as, but not limited to products with stipulated conditions on the CPR to be complied upon renewal registration shall not be applied or qualified for automatic renewal registration. In such cases, they shall be considered and processed as regular registration.

G. Automatic renewal application shall not apply also to the following:

- **Specialized Products**

1. Vaccines and Biological Products per AO No. 47-A s. 2001 Subject: Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products
2. In Vitro Diagnostic Reagents per AO No. 134 s. 2004 Subject: Guidelines Governing the Registration and Performance Evaluation of Drug Screening Test Kits and Reagents
3. Products with Bioavailability/Bioequivalence Problems [List B' (Prime)]. Submission of the following (whichever is applicable):
   - Multi Point Dissolution profile
   - Report of BA/BE study
4. Food Supplements per BC No. 16 s. 2005 Subject: Adopting the 2002 Recommended Energy and Nutrient Intakes as the New Dietary Standards
5. Infant Formula, Milk Supplements and Complementary Infant Food (for 6-12 months infants) per EO No. 51 Philippine Code of Marketing of Breast milk Substitutes

- **Products with post approval changes not covered under Section 2 (C) (1) of AO No. 2005-0030**

H. Renewal applications being referred to in the preceding paragraph and all other renewal applications that do not fall under automatic renewal category shall be processed under regular registration.

I. Automatic renewal applications shall be processed and released according to the specified time provided in Annex "A", except in cases when there is a need to issue another CPR.

II. REQUIREMENTS

A. Products for Automatic Renewal Application (Pharmaceuticals)

- **First Renewal**

1. Documentary Requirements

1.1 Forms to be accomplished correctly and completely
- 1.1.1 Revised Assessment Slip (Annex "B")
- 1.1.2 Notarized Application Form (Annex "C")
- 1.1.3 PART I ONLY of the BFAD PSDD Form (Annex "D")

1.2 Attachments
- 1.2.1 Copy of valid License to Operate
- 1.2.2 Original copy of Certificate of Product Registration
- 1.2.3 Copy of certification of approval on post approval change/s (if applicable)
- 1.2.4 Unattached and readable specimen of all labeling materials per pack size [e.g. outer, immediate, package insert (if applicable)

2. Technical Requirements

2.1 Actual Stability studies (3 production batches)

3. Specimen of the finished commercial product
(One specimen to represent the different pack size)

4. Electronic copy of Requirements 1-3 contained in Compact Disk (CD) properly labeled including **email address**.

☐ **Second Renewal and so forth**
All requirements under A (First Renewal) except 2.1

B. Products for Automatic Renewal Application (Medical Device)
All requirements under A (First Renewal) except 2.1

C. Products for Automatic Renewal Application (Prepackaged Food and Food Products)

1. Documentary Requirements

1.1 Forms to be accomplished correctly and completely
1.1.1 Revised Assessment Slip (Annex "E")
1.1.2 Notarized Application Form (Annex "F")

1.2 Attachments
1.2.1 Copy of valid License to Operate
1.2.2 Original copy of Certificate of Product Registration
1.2.3 Unattached and readable specimen of all labeling materials per pack size [e.g. outer, immediate, package insert (if applicable)

2. Specimen of the finished commercial product (One specimen to represent the different pack size)

3. Electronic copy of Requirements 1-2 contained in Compact Disk (CD) properly labeled including **email address**.

D. Products for Automatic Renewal Application (Household Hazardous Substances)
All requirements under A (First Renewal) except 2.1

III. PROCEDURE

A. Secure the proper forms either by downloading from the BFAD website *(http://www.bfad.gov.ph)* or by photocopying the existing prototypes.

B. Completely fill up the necessary forms. It should be typewritten

C. Arrange the documents according to the requirements in a color-guided long folder, using the following legend:
Orange : Pharmaceuticals
Red : Medical Device
Blue : Prepackaged Food and Food Products

In arranging the documents, put identifying markers/separators in between sections, indicating the type of document/s as per registration requirements.

D. Documentary, technical requirements set of representative sample/s in commercial presentation and a CD containing the requirement (For BFAD Automation Project) shall be placed in a resealable plastic envelope.

E. Application for automatic renewal registration shall only be received per BC 21 s. 2005 Subject: Cut-Off Time for the Receiving of Payments of Fees in BFAD.

This Bureau Circular shall take effect immediately.

PROF. LETICIA BARBARA B. GUTIERREZ, MS
Director

PROCEDURE IN PROCESSING AND RELEASING OF APPLICATIONS FOR AUTOMATIC RENEWAL REGISTRATION

1. All applications for automatic renewal registration received at the Public Assistance Information and Compliance Section (PAICS/Room 101) shall be forwarded at the different sections of the Product Services Division
   PREPACKAGED FOOD AND FOOD PRODUCTS – (Room 110)
   DRUGS, MEDICAL DEVICES AND HHS – (Room 106)

2. Assigned PSD staff shall assess the completeness and accuracy/correctness of the submitted documents.

3. Assigned PSD staff shall request for the duplicate copy of the Certificate of Product Registration (CPR) at Administrative Division - Records Section (Room 113).

4. The CPR of approved application shall be revalidated or a new CPR shall be issued.

5. Revalidated CPR shall be signed by the PSD Chief while re-issued CPR by the BFAD Director.

6. Signed CPR will be forwarded to Policy, Planning and Advocacy Division (PPAD) for encoding

7. PPAD will endorse the CPR to Administrative Division - Records Section for scanning

8. Administrative Division - Records Section will forward scanned CPR to Releasing Unit (Room 113)

All revalidated CPR(s) shall be released at the Releasing Section (Room100) according to the following schedule:

Receipt of Application		Release of CPR	
7:30 am	10:00 am	11:00	12:00
10:00 am	12:00 pm	2:00	3:00
1:00 pm	2:00 pm	3:00	4:00
2:00 pm	3:00 pm	4:00	5:00
After 3pm		The following day 9am – 10am	

PAICS COPY

Bureau of Food and Drugs
Policy, Planning, and Advocacy Division
ASSESSMENT SLIP
DRUG/VACCINE/VETERINARY/HERBAL

DATE: _____ RSN: _____

Applicant Company : _____
Address/Tel no. : _____
LTO No. : _____ Validity : _____

PRODUCT INFORMATION

Generic Name : _____
Brand Name : _____
Dosage strength and form : _____
Packaging : _____ Presentation : _____
Pharmacologic Category : _____ Registration No. : _____
Essential Drug : ☐ Yes ☐ No Classification : ☐ Rx ☐ OTC
Manufacturer : _____
Packer : _____
Repacker : _____
Trader : _____
Importer : _____
Exporter : _____
Distributor : _____
Suggested Retail Price : _____ No. of Samples : _____ Exp. Date : _____

APPLICATION DETAILS

Application Type	New Drug	Generic	Branded
Initial	☐	☐	☐
Renewal	☐	☐	☐
Renewal with Surcharge	☐	☐	☐
Re-application (**OLD RSN**: _____)	☐	☐	☐
Monitored Release	☐	☐	☐
Monitored Release Extension (MRE)	☐	☐	☐

No. of CPR Validity Applied for (year/s) _____

OTHER REQUESTS

☐ Amendment of CPR ☐ Certifications
☐ Brand name Clearance ☐ Provisional Permit to Carry
☐ Re-issued/Reconstruction of CPR ☐ Export Certificate
☐ Accreditation of BE Center ☐ Other, pls. specify _____

PAYMENT DETAILS

EVALUATOR		*CASHIER*	
Fee	: _____	Amount	: _____
Surcharge	: _____	OR Number	: _____
TOTAL	: _____	Date Issued	: _____
Evaluated by	: _____	Received by	: _____

RECEIPT DETAILS

Name and Signature : _____
Date : _____

ACCOUNTING SECTION'S COPY

Annex B

Bureau of Food and Drugs
Policy, Planning, and Advocacy Division
ASSESSMENT SLIP
DRUG/VACCINE/VETERINARY/HERBAL

DATE: _____ RSN: _____

Applicant Company : _____
Address/Tel no. : _____
LTO No. : _____ Validity : _____

PRODUCT INFORMATION

Generic Name : _____
Brand Name : _____
Dosage strength and form : _____
Packaging : _____ Presentation : _____
Pharmacologic Category : _____ Registration No. : _____
Essential Drug : ☐ Yes ☐ No Classification : ☐ Rx ☐ OTC
Manufacturer : _____
Packer : _____
Repacker : _____
Trader : _____
Importer : _____
Exporter : _____
Distributor : _____
Suggested Retail Price : _____ No. of Samples : _____ Exp. Date : _____

APPLICATION DETAILS

Application Type	New Drug	Generic	Branded
Initial	☐	☐	☐
Renewal	☐	☐	☐
Renewal with Surcharge	☐	☐	☐
Re-application (**OLD RSN**: _____)	☐	☐	☐
Monitored Release	☐	☐	☐
Monitored Release Extension (MRE)	☐	☐	☐

No. of CPR Validity Applied for (year/s) _____

OTHER REQUESTS

☐ Amendment of CPR ☐ Certifications
☐ Brand name Clearance ☐ Provisional Permit to Carry
☐ Re-issued/Reconstruction of CPR ☐ Export Certificate
☐ Accreditation of BE Center ☐ Other, pls. specify _____

PAYMENT DETAILS

EVALUATOR		*CASHIER*	
Fee	: _____	Amount	: _____
Surcharge	: _____	OR Number	: _____
TOTAL	: _____	Date Issued	: _____
Evaluated by	: _____	Received by	: _____

RECEIPT DETAILS

Name and Signature : _____
Date : _____

FOR AUTOMATIC RENEWAL REGISTRATION

For BFAD-PAICS use only	
RSN	

PROF. LETICIA-BARBARA B. GUTIERREZ, M.S.
Director
Bureau of Food and Drugs
Alabang, Muntinlupa City

Attention: PRODUCT SERVICES DIVISION
Drugs Section

Sir/Madam:

In accordance with RA 3720 and other related issuances, we wish to apply for the automatic 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 Date 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 taken 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. 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.
5. 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

6. No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
7. 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.
8. The person releasing the product for sale is an authorized and/or qualified person.
9. 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.
10. The marketing authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
11. The marketing authorization holder has a standard operating procedure for handling batch recalls of its products.
12. All the documentation referred to in this application is available for review during a GMP inspection.
13. Should the IPO or court of law of competent jurisdiction decide, with finality, that the applicant has no intellectual property right involving, or attached to, the pharmaceutical product, then any CPR/Marketing Authorization issued to the product in question shall be deemed automatically cancelled and/or revoked
14. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize said brand name;
15. We acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from its acceptance of such brand name or the registration of the pharmaceutical product concerned.
16. Product covered by this declaration will not undergo any change in the ownership, registrant's address/location, manufacturer, ingredients, pharmaceutical formulation, dosage form, strength, therapeutic indication, manufacturing process (if available), labeling or commercial presentation, and packaging of the product covered by the CPR without prior approval of this Office.

17. We acknowledge and agree that in the event that there is an unauthorized change in the ownership, its address/location, manufacturer, ingredients, pharmaceutical formulation, dosage form, strength, therapeutic indication, manufacturing process, labeling or commercial presentation and packaging of the product:

    i. BFAD may automatically suspend the LTO and/or CPR of the product;
    ii. We will voluntarily recall the product from the market; and
    iii. We will indemnify and/or hold BFAD free and harmless against any and all third party claims and/or actions pertaining to the above unauthorized change(s).

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 executed 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

Doc No. _____
Page No. _____
Book No. _____
Series of _____

Annex D

BUREAU OF FOOD AND DRUGS
PRODUCT SERVICES DIVISION – DRUG SECTION
BFAD-PSDD Form

BFAD USE ONLY

RSN :
Registration Number:
OR Number:
Amount:
Date Received:

PART I (Client Use only)

☐ Automatic Renewal ☐ Export

Generic Name:

Brand name:

Applicant Company

Manufacturer/ Repacker:

Importer / Distributor/ Trader:

PART II (BFAD Use)

I. Pre-Assessment

A.	Received	Compliant	Non-Compliant	Remarks
Documentary Requirements				
1. Revised Assessment slip				
2. Notarized Application Letter				
3. BFAD PSDD Form				
4. Copy of valid License to Operate				
5. Original copy of Certificate of Product Registration				
6. Copy of certification of approval on post approval change/s (if applicable)				
Technical Requirements				
1. Unattached and readable specimen of all labeling materials per pack size [e.g. outer, immediate, package insert (if applicable)]				
2. Specimen of the finished commercial product (One specimen to represent the different pack size)				
3. Actual Studies (3 production batches)				
***CD containing the submitted requirements**				

Assessed By/ date:

II. Recommendation

Final Evaluation (RECOMMENDATION) ☐ Approval ☐ Disapproval	Evaluated by/ date:

PAICS COPY

Bureau of Food and Drugs
Policy, Planning, and Advocacy Division
ASSESSMENT SLIP
FOOD

DATE: _____ RSN: _____

Applicant Company : _____
Address/Tel no. : _____
LTO No./Validity : _____

☐ Manufacturer ☐ Distributor/Wholesaler ☐ Importer ☐ Exporter ☐ Wholesaler

PRODUCT INFORMATION

Brand name and Product Name : _____
Product Classification (Category/Code) : _____
List of Products : _____
Number of Products Applied : _____
Packaging Types and Sizes : _____
Registration Number (FR) : _____ Validity: _____
Applicant Company : _____
Manufacturer : _____
Repacker : _____
Distributor : _____
Others (Pls. specify) : _____
Number of Samples : _____ Loose Labels: _____

APPLICATION DETAILS

Application Type	Category I	Category II	Food Supplement	Bottled Water
Initial	☐	☐	☐	☐
Renewal	☐	☐	☐	☐
Renewal with Surcharge	☐	☐	☐	☐
Re-application (**OLD RSN**: _____)	☐	☐	☐	☐

No. of CPR Validity Applied for (year/s) _____

OTHER REQUESTS

☐ Amendment of CPR ☐ Provisional Permit to Market (PPM)
☐ Re-issuance/Reconstruction of CPR ☐ Export Certificate
☐ Referral to ACB ☐ Others, pls. specify

PAYMENT DETAILS

EVALUATOR		*CASHIER*	
Fee	:	Amount	:
Surcharge	:	OR Number	:
TOTAL	:	Date Issued	:
Evaluated by	:	Received by	:

RECEIPT DETAILS

Name : _____
Signature : _____

ACCOUNTING SECTION'S COPY

Annex E

Bureau of Food and Drugs
Policy, Planning, and Advocacy Division
ASSESSMENT SLIP
FOOD

DATE: _____ RSN: _____

Applicant Company : _____
Address/Tel no. : _____
LTO No./Validity : _____

☐ Manufacturer ☐ Distributor/Wholesaler ☐ Importer ☐ Exporter ☐ Wholesaler

PRODUCT INFORMATION

Brand name and Product Name : _____
Product Classification (Category/Code) : _____
List of Products : _____
Number of Products Applied : _____
Packaging Types and Sizes : _____
Registration Number (FR) : _____ Validity: _____
Applicant Company : _____
Manufacturer : _____
Repacker : _____
Distributor : _____
Others (Pls. specify) : _____
Number of Samples : _____ Loose Labels: _____

APPLICATION DETAILS

Application Type	Category I	Category II	Food Supplement	Bottled Water
Initial	☐	☐	☐	☐
Renewal	☐	☐	☐	☐
Renewal with Surcharge	☐	☐	☐	☐
Re-application (**OLD RSN** _____)	☐	☐	☐	☐

No. of CPR Validity Applied for (year/s) _____

OTHER REQUESTS

☐ Amendment of CPR ☐ Provisional Permit to Market (PPM)
☐ Re-issuance/Reconstruction of CPR ☐ Export Certificate
☐ Referral to ACB ☐ Others, pls. specify

PAYMENT DETAILS

EVALUATOR		*CASHIER*	
Fee	:	Amount	:
Surcharge	:	OR Number	:
TOTAL	:	Date Issued	:
Evaluated by	:	Received by	:

RECEIPT DETAILS

Name : _____
Signature : _____

Annex F

COMPANY LETTER HEAD

The Director
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City
Alabang, Muntinlupa City

Attention: Product Services Division

Sir/Madam:

In accordance with RA3720 and other related issuances, we wish to apply for the RENEWAL registration of the following:

- ☐ CATEGORY I
- ☐ CATEGORY II

- ☐ LOCAL
- ☐ IMPORTED products:

Name of Product	Source of the Product		FR Number
	Name of Manufacturer	Name of Supplier	

Together with this application we are submitting the following:

- ☐ License to Operate
- ☐ Loose Label
- ☐ Sample of Product (only if required by BFAD for verification)
- ☐ Original Certificate of Product Registration

We categorically declare that all data and information submitted herewith are true and correct and any material misrepresentation or non-disclosure or omission of relevant information will render the application ineffective.

We also declare that the product/s do not contain ingredients and additives that are not permitted for use in human food in accordance with relevant regulations.

We understand and agree that the product/s may be subjected to BFAD laboratory examination at any time to verify the product's/products' safety, quality and conformity with labeling claims and that the cost of said examination shall be at our expense.

We also take full responsibility and accountability for the quality, safety and truth in the labeling declaration of the said food product/s.

For the product/s whose registration is being renewed, we declare that, no material change in formulation, labeling and technical specification in the said product/s was made.

Finally, we agree and bind ourselves that any material change in formulation, labeling, technical specification in the product in the future will be duly communicated and cleared with the BFAD.

_____ (Date).

Name of Company

By: Representative
(signature over name and designation)

Under oath and notarized