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REVISED PROCESS OF SUBMISSION OF APPLICATION FOR PRODUCT REGISTRATION

BFAD BUREAU CIRCULAR NO. 5, S. 1999, February 10, 1999

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In line with the present changes in the protocol for registration of products regulated by the BFAD, all concerned parties are hereby advised of the new process to be adopted at the PAICS:

- All applications for registration shall be submitted at the PAICS according to the following schedule:

Food Products Monday (whole day)

Pharmaceutical Products

(Drugs, Medical Devices, Diagnostic Reagents)

Tuesday

A.M. — Company names starting with A-E

P.M. — Company names starting with F-M

Wednesday

A.M. — Company names starting with N-Q

P.M. — Company names starting with R-Z

Cosmetic Products Thursday (whole day)

Household Hazardous Substances Thursday (whole day)

- Applicant companies shall be entertained on a "first-come — first serve" basis with a maximum of five applications per company for pharmaceutical products. A slot number shall be issued to the liaison officers to ensure order.

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- Applications shall be supported by one complete set of documents as enumerated in the applicable checklist of requirements for product registration and a representative sample (in commercial presentation) for PSD evaluation.

These requirements shall be contained in a plastic bag/envelope for ease in handling.

- In addition to the above requirements, the applicant company shall submit an accomplished PAICS Form No. 99-01 "Classification of products for registration with corresponding fees", which shall be used as basis for the issuance of order of payment by the PAICS staff.

- Upon issuance of the Order of Payment, the applicant company shall proceed to the Accounting Section for checking and then to the Cashiers Office for payment of corresponding fees.

- The official receipt of payment shall be presented to the PAICS staff for final acceptance of the application and issuance of the routing slip number (RSN).

- For pharmaceutical products being applied for renewal registration, the CPR shall be stamped "received" by a PAICS staff.

- Follow-up or inquiries on the status of application received starting February 04, 1999, shall only be entertained 3 months (90) days after such application was received. A follow-up form issued by the PAICS shall be used for this purpose.

- All applicants are reminded that applications shall be received at the PAICS without pre-assessment by PSD. The application requirements and PAICS Form 99-01 shall be presumed to be correct and complete. PAICS and PSD staff will not accept additional documents after the application has been received by PAICS.

- PSD shall issue an approval or disapproval of the application based on the completeness and accuracy of documents and the truthfulness and acceptability of information contained therein. Abeyance letters shall no longer be issued.

- This order shall take effect immediately.

Adopted: 10 Feb. 1999

(SGD.) WILLIAM D. TORRES, PH.D.
Director

CLASSIFICATION OF PRODUCT FOR REGISTRATION WITH CORRESPONDING FEES
Listed below are the different classification of products for registration with the corresponding fees. Please tick the product classification and registration classification of your application and attach this form to the application letter (original). This shall be used by PAICS in preparing the order of payment.

Product Name: _____

Expiration Date of CPR (for Renewal Registration): _____

[ ] Processed Food

[ ] Initial P25.00

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[ ] P25.00

[ ] Bottled Water

[ ] Initial P300.00

[ ] P500.00

Pharmaceutical Products

[ ] Monitored Release

[ ] Initial P6,000.00

[ ] Generic Drug

[ ] Initial P2,500.00

[ ] Renewal P1,500.00

[ ] Branded Drug

xxxxxxx

[ ] Renewal P1,500.00

[ ] Diagnostic

Reagent

[ ] Initial P 25.00

[ ] Renewal P25.00

[ ] Medical Device

[ ] Initial P55.00

[ ] Renewal P150.00*

x

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[ ] Cosmetics

[ ] Initial P55.00

[ ] Reg'n

Renewal P150.00

[ ] Listing Renewal P55.00

[ ] Household Hazardous Substance

[ ] Initial P55.00

[ ] Renewal P55.00

1. For pharmaceutical products being applied for renewal registration:

> 1.1 A surcharge equivalent to 50% of the renewal fee shall be imposed on applications filed one day and up to 3 months after the expiration of the CPR.
>
> 1.2 Application filed more than three months after the expiration of the CPR shall be considered and charged as initial registration.

2. Any excess in the amount collected from the applicant company as a result of the information given in this form by the undersigned shall be non-refundable. However, in case a deficiency is noted resulting in under payment of fees, the BFAD shall collect from the company additional fee prior to the release of the CPR.

_____

_____

Name of Company

Printed Name and Signature

of Representative

Date:

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