

[BFAD BUREAU CIRCULAR NO. 2, S. 1995, May 15, 1995]

**CANCELLATION OF 1988-1989-1990 INACTIVE APPLICATIONS
FOR PRODUCT REGISTRATION**

In line with the Product Services Division's (PSD) pursuit to streamline the Systems and Procedures of Product Registration, all inactive applications for product registration filed before 2 January 1991 (initial or renewal, with or without MOE) shall be dropped from the pool of registration applications on 01 July 1995.

All companies which have not received final action of approval or denial on their 1988-1989-1990 registration applications are hereby advised to reactivate their applications by filing a notice of application reactivation, as shown on the attached form marked Annex "A", on or before 30 June 1995.

All documents submitted for the applications which shall not be reactivated or retrieved by the applicant company before the stated date shall be removed from the PSD files and destroyed to prevent any possibility of breaching the applications confidentiality.

The following PSD evaluators shall accept notices of 1988-1989-1990 application reactivation:

1. GRACE MEDINA
2. MARIVIC PAULINO
3. EDEN ROBLES
4. ALMA AGUINALDO
5. FRANCE LABOY

Implementation details of this Circular is likewise attached as Annex "B" for the guidance of parties concerned.

Adopted: 15 May 1995

(SGD.) QUINTIN L. KINTANAR, M.D., PH.D., CESO I
Director

Annex "A"

NOTICE OF 1988-1989-1990 APPLICATION REACTIVATION

PRODUCT NAME: _____

RSN: _____

NAME OF COMPANY: _____

Last known status of application:

/ / Held in abeyance due to incomplete documents: Date of compliance (if any)

/ / Product samples being analyzed at LSD: Samples submitted to LSD on

/ / Referred to ACB: Date referred _____

Documents submitted:

/ / No action

Name of evaluator (if known) _____

Name and Signature of Company's Responsible Officer

For PSD use only

Received by: _____

Date: _____

Current status of application: _____

Additional requirements to be submitted by company:

1. Unit dose formulation
2. Technical specifications of finished product
3. Generic labelling materials
4. Report of stability studies
5. Samples of analysis
6. Certificate of analysis of samples
7. Others: _____

Action Taken:

1. Documents / / located / / not located
2. Informed company representative of deficiencies; date _____
3. Additional requirements/samples received from company; date _____
4. Forwarded complete documents/samples to Ms. T. Gutierrez for decking; date _____

Annex "B"

**SUBJECT: IMPLEMENTING GUIDELINES FOR THE CANCELLATION OF
INACTIVE 1988-1989-1990 APPLICATIONS FOR DRUG PRODUCT
REGISTRATION**

1. Filing of Notice of Application Reactivation

Companies desiring to reactivate an application for drug registration shall file a notice of application reactivation (NAR) using the form provided by the PSD (see attached form) to be filled out in duplicate. The accomplished forms shall be submitted to the PSD evaluator on duty. Notices shall be received by a PSD evaluator according to the following schedule: