

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

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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:

MONDAYS - GRACE MEDINA

TUESDAYS - MARIVIC PAULINO

WEDNESDAYS - EDEN ROBLES

THURSDAYS - ALMA AGUINALDO

FRIDAYS - FRANCE LABOY

The company representative shall be advised to call up the PSD evaluator three (3) days after filing the NAR for

information on the current PSD status of the application in question.

2. Reactivation Procedure

2.1.

Daily accumulated notices (NAR) shall be processed by the evaluator who received the accomplished form. Depending on the last known status of the application, PSD evaluator shall locate all files of subject application and inform the concerned company of the actual status of the application three (3) days after filing of the NAR.

2.2

The following procedure shall be followed in processing the NAR:

2.2.1 Application being held in abeyance due to incomplete documents

Evaluator shall locate file in PSD

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Can't locate file

File available

-check if lab analysis had been done

-issue copy of abeyance letter to company

-if, yes, request the ff. documents from Co.

-request compliance to stated requirements within 30 days

-formulation

-inform Co. that no compliance within 30 days shall mean final cancellation of application unless justified reason can be given within the 30-day period

-technical specs of finished products

-reports of stability studies

-generic labelling materials

-copy of Official Receipt

-if no, request above, documents on samples, C.A. of sample

2.2.2 Sample Forwarded to LSD

Evaluator shall determine if sample was forwarded to the laboratory and when it was sent for analysis

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forwarded to LSD within the last 6 mos.

forwarded to LSD > 6 mos. ago

-determine if

-check if lab analysis report was received

a) lab analysis had been done

-locate or request for copy of lab result

-if yes, check if all other docs. are complete; inform Co. of any other requirements

b) spl is scheduled for analysis

-if no, request new samples for analysis

c) spl had expired

-request for sample, C.A.

2.2.3 Referred to ACB

Evaluator shall determine when documents were submitted to ACB and for what purpose

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Forwarded to ACB within the last 6 mos. ago

forwarded to ACB more than 6 months

-inform ACB that application should be given priority

-check if ACB still has documents

-if yes, inform ACB that application should be given priority

-if no, request new set of documents from the the Company

2.2.4 No Action

If no action by the PSD can be identified, Company shall be requested to submit a complete set of application requirements for PSD and LSD evaluation.

2.3

If additional documents or samples for analysis shall be required, this shall be submitted by the applicant company within 30 days after they were informed of said requirements. Non-compliance within the said period shall mean final cancellation of the subject application unless justified reasons are given in writing within the 30-day period.

2.4

Completed applications shall be submitted by the evaluator to Ms. T. Gutierrez for decking. Evaluation of completed applications shall be given top priority by the ACB, PSD and LSD.

3. Final Cancellation/Destruction of Inactive 1988-1989-1990 Applications

3.1

All 1988-1989-1990 applications which shall remain inactive after 01 July 1995, shall be finally cancelled and removed from the PSD files.

3.2

All fees paid for the cancelled applications shall be forfeited in full as provided under Section 6 of A.O. 67 s. 1989.

3.3

A list of cancelled applications shall be posted at the BFAD bulletin board two weeks before the actual date when all documents pertaining to these applications shall be destroyed. Destruction of these documents shall be done by assigned PSD staff in the presence of representatives from the LAD and applicant company at a date which shall

be announced later.

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