REVISED IMPLEMENTING GUIDELINES FOR THE EFFECTIVE IMPLEMENTATION OF A.O. NO. 151 S. 1971

BFAD MEMORANDUM CIRCULAR NO. 9, August 17, 1990

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RE: CERTIFICATION OF ANTIBIOTICS

To facilitate effective implementation of A.O. No. 151 s. 1971, the guidelines provided for under Memo Circular No. 14 s. 1989 and Memo Circular No. 4 s. 1990 are hereby revised or modified as follows:

- The applicant for batch certification shall comply with the following requirements:

1.1 Accomplish BFAD BCA Form No. 1 which is the application form that would indicate required information for the issuance of batch certification.

1.2 Submit the complete terminal quality control record of the batch to include all requirements of the official monograph.

The complete production record and in-process control record of the batch concerned may not be submitted but must be made available to BFAD Food and Drug Regulation Officers upon inspection.

- Batches of antibiotics and products containing antibiotics may only be certified after BFAD Laboratory Analyses showing that the batch applied for conforms with the registered specification and BFAD Standards.

- The required laboratory analyses may be waived if after evaluation of the documents submitted, the Director, upon the recommendation of the Chief Laboratory Services Division, finds the results of the tests and assay submitted satisfactory and reliable, Provided, however, that:

3.1 the applicant manufacturer, trader, or importer has no record of violation of any law, rules and regulations implemented or administered by BFAD;

3.2 and the product has no record of deficiency or violative laboratory findings;

3.3 validation of the submitted results is reserved and shall be conducted on samples to be submitted, the quantity of which is specified, hereunder, thus:

3.3.1 Six (6) bottles of suspension/syrup

3.3.2 One (1) bottle x 100’s or 2 bottles x 50’s for tablets/capsules or equivalent number of stripped/blister pack form

3.3.3 Six (6) vials ampules for injectable form

3.3.4 Four (4) tubes for ointment/cream

Request for Exemptions on the amount of samples may be considered available for BFAD Food and Drug Regulation Officers upon inspection.

- Proper recording required under Section C-7.1.5 of A.O. 151 s. 1971 shall be administered by BFAD Laboratory Services Division.

- Application for batch certification may be denied only upon Laboratory Services Division findings showing that the product sought to be certified:

5.1 does not conform with the registered specifications;

5.2 does not bear the batch number, date of manufacture and expiry date;

5.3 does not indicate the correct batch size.

- Denial of batch certification may be reconsidered only when:

6.1 the defect does not affect the safety, efficacy, purity and quality of the product; and

6.2 the correction of the defect has been properly verified.

- This Circular supersedes Memo Circular No. 14 s. 1989 and Memo Circular No. 4 s. 1990 and shall take effect immediately upon approval.

Adopted: 17 Aug. 1990

(SGD.) CECILE P. GONZALEZ

Director

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