Republic of the Philippines
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
D. O. H. Compound
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BUREAU CIRCULAR
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TO       ALL DRUG MANUFACTURERS, TRADERS
         AND DISTRIBUTOR-IMPORTERS

SUBJECT  IMPLEMENTATION DETAILS OF BFAD
         CIRCULAR NO.1. S. 1997

For a reasonable enforcement of the requirements for bioavailability study on
drug products under the List B, the BFAD has decided on the following guidelines:

1. Beginning January 22, 1997, applications for initial registration including
   those for conditional registration due to a chance of manufacturer, of drug
   products in List B shall not be accepted without a satisfactory report of
   bioavailability study.

2. Applications for initial registration of drug products which are pending as of
   January 21, 1997, and which have passed the usual tests as well as other
   requirements except for a satisfactory report of bioavailability study, shall
   be granted Conditional Certificate of Product registration for one (1) year.
   This certificate shall be subject to the condition that the applicant company
   shall submit a satisfactory report of bioavailability study within the period of
   one year from the date of issue.

3. Applications for renewal registration which pass all test and other
   requirements including satisfactory bioavailability studies shall be granted
   renewal registration valid for a period of five (5) years.

   3.1 However, application for renewal registration of drug product in List B
       which pass all the test and other requirements but have no reports of
       bioavailability studies because of the lack of bioavailability testing
       unit/laboratory, shall be granted a conditional renewal registration valid
       for five (5) years; Provided, that the applicant shall present a copy of its
       request for bioavailability testing of the said product addressed and
       received by a recognize testing unit. This conditional renewal
       registration shall be subject to outright suspension in case the product
       will fail in the bioavailability study.

4. Considering that bioavailability study is one among the test on the quality
   and efficacy of the drug product in List B, the Bureau confirms that the
   registration of a drug product that fails in the bioavailability study will be
   suspended until the same product passes the said study satisfactorily.

5. The drug product in List B’ are subject to review and revision by the
   National Drug Committee

This is for the information and guidance of all concerned.

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