[BFAD BUREAU CIRCULAR NO. 8, S. 1997, April 30, 1997]

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

For a reasonable enforcement of the requirement 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 change 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 tests and other requirements including satisfactory bioavailability studies shall be granted renewal registration valid for a period of five (5) years.

3.1 However, applications for renewal registration of drug product in List B1 which pass all the tests 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 requests for bioavailability testing of the said product addressed and received by a recognized 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 tests on the quality and efficacy of the drug product in List B1 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 products in List B1 are subject to review and revision by the National Drug Committee.

This is for the information and guidance of all concerned.

Adopted: 30 April 1997