[BFAD BUREAU CIRCULAR NO. 01, S. 1997, January 21, 1997]

ENFORCEMENT OF THE REQUIREMENT FOR BIO-AVAILABILITY STUDIES FOR REGISTRATION OF PRODUCTS INCLUDED IN THE LIST B' (PRIME) UNDER DOH-ADMINISTRATIVE ORDER NO. 67 SERIES OF 1989

In Annex 1 of A.O. 67 s. 1989 which is entitled Requirement For Registration provides the "Bioavailability/Bioequivalence study for certain drugs as determined by BFAD" is required for Tried and Tested Drug, (ii) Established Drug, and (iii) Pharmaceutical Innovation of Tried and Tested or Established Drug.

Drugs requiring strict precaution in prescribing and dispensing contained in the List-B (Prime) were the drugs identified by BFAD in the process of registration that will be required Bioavailability/Bioequivalence studies. However, due to the supervening factor that there has yet been no bioavailability testing unit in the country when the A.O. 67 s.1989 became effective, the Bureau did not strictly enforce the said requirement.

The supervising factor no longer exists as of date. As a matter of fact, one of the registered products tested by the Bioavailability Testing Unit at the University of Sto. Tomas under the NDP Cooperation Project of the Philippines and Australia failed to meet the standard of bioavailability. This finding brings forth the fact that there may be registered products which do not or may no longer meet biovailability standard.

Wherefore, all drug manufacturers, traders, distributor-importers of product contained or identified in the list b' (prime) provided for by BFAD, a copy of which is made part of this circular, are advised that all pending initial and renewal registration of the products aforementioned, as well as all applications for initial and renewal registration of the same, shall henceforth be required to submit bioavailability tests with satisfactory results on the products sought to be registered or renewed conducted by any bioavailability testing units here or abroad, duly recognized by the BFAD under the Dept. of Health.

Adopted: 21 Jan. 1997

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