[BFAD BUREAU CIRCULAR NO. 2006-008-A, October 08, 2007]

AMENDMENT TO BUREAU CIRCULAR NO. 008, S. 2006, THE SUBJECT OF WHICH IS THE "LIFTING OF MORATORIUM ON THE CONDUCT OF BIOAVAILABILITY/BIOEQUIVALENCE STUDIES FOR SELECTED PHARMACEUTICAL PRODUCTS AND BUREAU CIRCULAR NO. 2007-005 OR THE "SUPPLEMENTAL GUIDELINES FOR THE PROCESSING OF PRINCIPAL CERTIFICATE OF PRODUCT REGISTRATION", AND PROVIDING FOR THE PROCEDURES AND/OR GUIDELINES THEREOF

I. Rationale

Bureau Circular No. 008, s. 2006, which lifts the moratorium on the conduct of bioavailability/bioequivalence studies for selected pharmaceutical products, was issued in recognition of the availability of facilities and bioanalytical methods to be used in the conduct of bioequivalence studies.

On the other hand, Bureau Circular No. 2007-005, which implements Administrative Order No. 2005-31 or the Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of the Manufacturer and Pharmaceutical Formulation, requires the conduct of Bioavailability/bioequivalence studies of drug products that are likewise listed in Bureau Circular No. 008 s. 2006 and are prospectively to be covered by Principal Certificates of Product Registration.

As such, the sudden deluge of applications for Bioavailability/Bioequivalence studies accordingly makes the conduct of studies to be scheduled months apart. This scenario leads to the delay of issuance of Certificates of Product Registration (CPR) and if permitted to continue, this may eventually hinder the government's policy to lower the costs of medicines identified in Bureau Circular No. 008, s. 2006, this amendment.

II. Amendments/Guidelines

Item II, (A) of Bureau Circular No. 008, s. 2006 on Initial Registration is hereby amended to read as follows:

A. Initial Registration

1. All new and pending applications for initial registration of products listed in Bureau Circular No. 008 s. 2006 which were already scheduled for BA/BE studies and awaiting the results thereof shall be issued a Certificate of Product Registration (CPR) which will be valid only for one (1) year without extension, unless if the BA/BE study cannot be completed within one (1) year from the date of the issuance

of the CPR, in which case, only one extension is allowed and only for another year; provided that the applicants shall have fully complied with the following requirements and the same have passed evaluation by the proper division of the Bureau, to wit:

a. The applicant have completed all other documentary requirements for the purpose;

b. The applicant shall submit proof of payment of the requisite BA/BE studies with the corresponding schedule. The schedule must indicate the date when the study shall be expected to be completed;

c. The applicant shall submit complete data (e.g. graphs, assay methods) of comparative dissolution profiles (reference innovator product versus product to be registered). The dissolution profiles should be performed using the parameters identified in Bureau Circular No. 13-A s. 1999; and

d. The applicant shall execute and submit a duly notarized Affidavit of Undertaking containing the following:

Agreement

i) that in the event the result of the BA/BE study fails, or there has been verified report/s of serious adverse events (serious physical injuries or death) and the proximate cause thereof is the use of the product under study, or there is findings of misrepresentation or falsification by the applicant on the data or any document it tendered with the BA/BE center in connection with the conduct of the study as well as the result submitted with the Bureau, the CPR so issued shall be revoked or cancelled immediately at the instance of the Bureau and delisting of the registration of the product from the database without notice and hearing;

ii) to voluntarily surrender the CPR issued and recall or withdraw voluntarily from the market the product covered by said CPR pursuant to Bureau Circular No. 08 s. 2001;

iii) to indemnify and/or hold BFAD free and harmless against any and all

third party claims and/or actions pertaining to the above incident and action of the applicant;

iv) that the applicant is aware that this Office is not precluded and can, at any time even when an amended CPR is already issued pursuant to paragraph two (2) below, validate and inspect with the BA/BE center the data or any document it tendered with said center in connection with the conduct of the study as well as the results of the study submitted with the Bureau; and

v) that if the CPR expires without securing favorable extension from the Bureau, to voluntarily cease and desist from further manufacturing, importing, exporting, selling, offering for sale, distributing, or transferring