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02 April 2007

BUREAU CIRCULAR
NO. 2007-005

SUBJECT : Supplemental Guidelines for the Processing of Principal Certificate of Product Registration (CPR)

I. RATIONALE

The Bureau of Food and Drugs (BFAD) was tasked under Administrative Order No. 2005-0031 to simplify and expedite the registration of pharmaceutical products based on the identity of the manufacturer and of the same pharmaceutical formulation by linking them, if applicable, to the Principal CPR. As such, the BFAD issued Bureau Circular (BC) No. 011 s. 2006 to operationalize AO No. 2005-0031.

In the implementation of AO No. 2005-0031, the BFAD has encountered issues wherein certain products that are prospectively to be covered with Principal CPRs are considered as requiring Bioavailability/Bioequivalence (BA/BE) studies per Bureau Circular No. 8 s.2006. The conversion of Regular CPRs to Principal CPRs for products that are covered by BC No. 8. s. 2006 leads one to ask when should a Bioavailability/Bioequivalence study be conducted so that such reckoning date will be consistent with the validity dates of CPRs. An algorithm is therefore necessary to determine what would trigger the conduct of the test based on existing validity period of the CPRs.

Further, the fees that shall be collected for application of Principal CPRs must be rationalized taking into consideration that remaining validity period of the converted Regular CPRs to ensure fairness.

II. OBJECTIVES

The objectives of this Order are:

1) To provide the basis in requiring the conduct of bioavailability/bioequivalence studies with reference to the validity dates of CPRs;

2) To provide basis for payment of fees on application for Principal CPRs; and

3) To ensure common understanding and application of regulatory rules.

III. GUIDELINES

1. Conversion of Regular CPRs into Principal CPRs of products **not** covered by BC No. 8 s. 2006 shall be processed immediately upon payment of a fee for amendment.

2. Products that are covered by BC No. 8 s. 2006 shall be processed by observing the following conditions:

    a. Firms which are holders of Regular CPRs and have applied for the conversion of their existing CPRs into Principal CPRs and whose existing CPRs have remaining validity period of less than or equal to two and a half (2.5) years, shall be issued with a Principal CPR with the condition that they shall submit a schedule of BA/BE studies upon the renewal. A fee for an amendment shall be paid by the firm in such an instance.

    b. Firms which are holders of Regular CPRs and have applied for the conversion of their existing CPRs into Principal CPRs and whose existing CPRs have remaining validity period of more than two and a half (2.5) years, shall be issued with a Principal CPR with the condition that they shall submit a completed BA/BE studies upon the renewal. A fee for an amendment shall be paid by the firm in such an instance.

    c. For firms with no existing Regular CPR and have applied for a Principal CPR shall be issued a Principal CPR but must submit a completed BA/BE study upon application. A fee equivalent to what is exacted for an application of Regular CPRs shall be paid by the firm in this instance.

    d. For firms with Regular CPRs that have failed to renew their CPRs beyond the allowable period of time for filing or whose CPRs are effectively expired shall be issued a Principal CPR but must submit a completed BA/BE study upon application. A fee equivalent to what is exacted for an application of Regular CPRs shall be paid by the firm in this instance.

IV. REPEALING CLAUSE

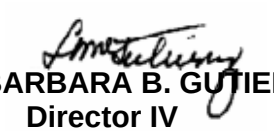
All provisions of previous issuances which are inconsistent with those prescribed in this Order are hereby repealed and modified accordingly.

V. SEPARABILITY CLAUSE

Any provision of this Order, which may be rendered invalid, illegal or unconstitutional, the remaining unaffected provisions shall still be in effect.

VI. EFFECTIVITY

This Order shall be effective immediately.



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