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REGISTRATION OF BRANDED VERSION OF REGISTERED UNBRANDED GENERIC DRUG PRODUCT, AND GENERIC VERSION OF REGISTERED BRANDED DRUG PRODUCTS

BFAD MEMORANDUM CIRCULAR NO. 10-A, June 01, 1992

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1. A manufacturer, Trader or Distributor-Importer who has a registered unbranded generic drug product may apply for registration of the branded version of the said product PROVIDED that if the registration of that generic product was processed through the Special Lane (MC No. 5 s. 1990) under product category b, the registration of the branded version will become effective only one (1) year from the date of application for the branded version, but not less than one (1) year after the date the generic version was approved. (Product category b under MC No. 5 s. 1990 is a special privilege for generic (unbranded) drug product, hence this rule.

1.1

The applicant shall submit together with his application a copy of the (a) brand name clearance, and (b) the current Certificate of Product Registration (CPR) of the unbranded generic drug product and (c) a prototype of the proposed complete commercial form and presentation of the branded version of the product including labels and inserts.

1.2

In case the generic drug product was approved through the Special Lane under product category b, MC No. 5 s. 1990, the application shall also be accompanied by a copy of the approval of the registered product's application under special lane.

1.3

A CPR will be issued for the branded version with the same CPR number qualified by the letter "B".

2. A Manufacturer, Trader or Distributor-Importer who has a registered branded drug product may apply for registration of the unbranded generic version of the same.

2.1

The applicant shall submit together with his application (a) a copy of the current CPR of the branded version (b) a prototype of the proposed complete commercial form and presentation of the unbranded generic version of the product, including labels and inserts.

2.2

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A CPR will be issued with the same CPR number of the branded version qualified by the letter “G”.

3. Registration fees prescribed by Administrative Order 67 s. 89 will likewise govern these applications.

4. Registration index cards will be created for the branded or generic versions but the formulation and specifications shall be identical with their branded or generic versions previously registered, such that the products file for the branded and generic version shall only be one and the same.

This regulation is issued in accordance with AO 67 s. 89 and shall be effective immediately upon approval.

Adopted: 1 June 1992

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