STANDARD POLICY ON LABELED POTENCY OF PHARMACEUTICAL PRODUCTS

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Records of this Office show that one of the main reasons for the disapproval/denial of initial and renewal registration is due to its failure to meet potency specifications.

For example, in the case of Amoxicillin preparations, the amount of Amoxicillin trihydrate used must be equivalent to the amoxicillin base that will provide the required dosage strength (e.g. 500 mg Amoxicillin base requires 574 mg of the trihydrate form).

Henceforth and effective immediately, it is hereby reiterated that all formulations of pharmaceutical products registered with this Office must be in accordance with the potency requirements of the monograph of the product as officially listed in USP, BP and EP pursuant to AO 67, s. 1989 and in such other official compendia as may be recognized by BFAD.

Adopted: 03 Aug. 2000

(SGD.) WILLIAM D. TORRES, Ph.D.
Director

Noted:

(SGD.) ALBERTO G. ROMUALDEZ, JR. M.D.
Secretary of Health

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