VALIDITY PERIOD OF PROVISIONAL REGISTRATION OF FIXED-DOSED COMBINATIONS (FDCs)

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This is to confirm the decision of the Bureau of Food and Drugs in April 1993 to set the validity period of the provisional registration granted to FDC drug product, as follows:

I. For products classified under priority I by A.O. No. 96 s. 1990, the validity period is one (1) year; and

II. For products classified under priority II and III by the same A.O., the validity is five (5) years.

This is issued for the guidance of all concerned.

Adopted: 12 Aug. 1993

(Sgd.) QUINTIN L. KINTANAR, M.D., PH.D., CESO I
Director

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