



Republic of the Philippines  
Department of Health  
**BUREAU OF FOOD AND DRUGS**  
Filinvest Corporate City  
Alabang, Muntinlupa City

Bureau Circular  
No. 5 s. 2002

TO : ALL MANUFACTURERS, IMPORTERS AND DISTRIBUTORS OF IN-VITRO DIAGNOSTIC REAGENTS/KITS

SUBJECT : **EXTENSION OF THE VALIDITY PERIOD OF INITIAL AND RENEWAL REGISTRATION OF IN-VITRO DIAGNOSTIC REAGENTS/KITS**

The current validity period for both initial and renewal registration of In-Vitro Diagnostic Reagents is one (1) year, except for HIV Test Reagents/Kits which are issued a two (2) year validity provided in Memorandum Circular No. 11s. 1994.

BFAD considers, however, that the quality and safety of these In-Vitro Diagnostic Reagents/Kits vis-a-vis their intended use have been evaluated and their performance characteristics have been found satisfactory before they are approved for initial registration.

We find it proper, therefore, to adopt the recommendation of the industry to extend the validity period of registration of these products, including HIV Test Reagents/Kits. The applicant company shall have the option to choose the validity period for their period as 2, 3, 4 or 5 years for initial and 3, 4, or 5 years for renewal registration.

This Circular shall cover all applications for initial and renewal registration after the date of its signing as well as those that are pending registration as of the same date.

This Circular does not preclude the BFAD from imposing certain conditions, whenever necessary, in the Certificate of Product Registration relating to the product's quality and safety.

All other circulars, rules, regulations, issuances, or parts thereof, inconsistent with the provisions of this bureau Circular, are hereby repealed or modified accordingly.

**(Sgd) WILLIAM D. TORRES, Ph.D.**  
Director IV

Date signed: April 4, 2002