[BFAD (DOH) MEMORANDUM CIRCULAR NO. 11, s. 1994, May 23, 1994]

JOINT BFAD-RITM OPERATIONAL PROCEDURE FOR REGISTRATION OF HIV TEST SYSTEMS

The Bureau of Food and Drugs (BFAD) In Joint efforts with the Research Institute for Tropical Medicine (RITM) has developed an operational procedure for registration of HIV test systems with the end-in-view to streamline the evaluation and registration process of HIV testing products.

The following shall serve as the BFAD-RITM Operational Procedure for registration of HIV test systems:

1. Acceptance of application for registration at the Public Assistance, Information and Compliance Section (PAICS) - BFAD with payment of registration fee only.

2. Preliminary evaluation of documents at the Product Services Division (PSD) - BFAD.

3. Second copy of all required documents shall be forwarded to the RITM with an endorsement letter from the BFAD Director.

4. RITM shall issue a "Notice for Submission of Samples" to the applicant company and shall furnish BFAD with a copy of said notice.

5. Request for Analysis shall be forwarded by RITM to BFAD - PSD for final action on the registration application.

6. RITM shall be furnished with a copy of BFAD's final action on the registration application.

For the *procedure of registration* of HIV Test System, the following shall be observed:

1. Secure a license to operate as Drug Importer/Distributor from the Regulation Division I (Reg. Div. I) of the Bureau of Food and Drugs (BFAD).

2. Secure a Certificate of Brand Name Clearance from the Product Services Division (PSD) - BFAD If the product to be imported/ distributed carries a brand name.

3. Submit an application for product registration at the Public Assistance and Compliance Section (PAICS)-BFAD together with all the requirements for preliminary evaluation listed on the checklist of requirements for registration of HIV test systems.

4. Upon receipt of the "Notice for Submission of Samples", submit the requirements for performance evaluation at the National Reference Center for HIV Testing, Virology Section of the Research Institute for Tropical Medicine (RITM).

5. The Certificate of Product Registration (CPR) with a Two (2) Year Validity shall be issued upon completion of evaluation by BFAD and RITM.

A Checklist of Requirements is appended as ANNEX "A" into this Memorandum Circular as a guide to HIV Test Systems Importer/ distributor.

Adopted: 23 May 1994

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

Checklist of Requirement for Registration of HIV Test Systems

Manufacturer_____
Importer/Distributor_____
Product Name_____

I. PRELIMINARY EVALUATION REQUIREMENTS

one copy 1. Letter of application from the Importer/distributor

one copy 2.* License to Operate as Importer/ distributor of drug product

one copy 3.* Government certificate of clearance arid free sale/registration approval of the product from country of origin; and duly authenticated by territorial Philippine Consulate

one copy 4.* Government certificate attesting to the status of manufacturer, competency and reliability of its personnel and facilities, and duty authenticated by territorial Philippine Consulate

one copy 5.* Certificate of agreement between the manufacturer and the Importer/distributor regarding the product

one copy 6.* Certificate of brand name clearance

one copy 7**. Latest Certificate of Product Registration

two copies 8. Evaluation report from any of the following:

a. WHO Collaborating Center for HIV, Antwerp, Belgium

b. WHO Collaborating Center for HIV, Fairfield, Australia