

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

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

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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 and 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 duly 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
- c. US Food and Drug Administration
- d. Swedish Institute for Infectious Disease Control (formerly National Bacteriological Laboratory), Stockholm, Sweden
- e. National HIV Reference Laboratory, Central Public Health Laboratory, London, U.K.
- f. Paul Erlich Institute, Langen, Germany

two copies. 9. Data from routine use of the kit in other countries

two copies 10. List of all raw materials used as components of the test kit

two copies 11. Product specifications and physical description of the finished product

two copies 12. Flow chart of the manufacturing procedure

two copies 13. Routine quality control tests on components of the kit and/or assembled kit prior to release

two copies 14. Stability studies of the product to justify claimed shelf life

two copies 15. Unattached actual labelling materials (box/carton, label of each component of the kit,- insert, brochures, etc.)

one copy 16. Evidence of registration fee payment

II. PERFORMANCE EVALUATION REQUIREMENTS (to be submitted to RITM upon receipt of the "Notice for Submission of Samples")

1. Test kits

1.1 Should accommodate at least 450 tests

1.2 Should be of the same lot number

1.3 Expiration date should be at least three (3) months from the date of submission

1.4 Should be transported/received intact and in cold packing

1.5 For HIV-1/HIV-2 combination kits, submission of five (5) HIV-2 seropositive sera, 0.5 mL each

2. Evidence of payment of P7,000.00 for laboratory test fee.

PROCEDURE FOR REGISTRATION OF HIV TEST SYSTEMS

1. Secure a license to operate as drug importer/ distributor from the Regulations Division II (REG II) 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, Information 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 shall be Issued upon completion of evaluation by BFAD and RITM

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. Result of 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

Filed: 26 August 1994

Memorandum Circular No. 12, s. 1994

Addendum to BFAD Memo Circular No. 4, s. 1994

As an amendment to BFAD Memo Circular No. 4, s. 1994 re: Amendment to MC No. 1. s. 1994: Compliance with the IRR of the Senior Citizens Act, the following additional information shall be Incorporated:

1. Letter (e) line 4 shall read: "provided by the DSWD or OSCA effective July 1 - September 30, 1994 which shall be prescribed as the transition period and eventually becomes mandatory by October 1, 1994."
2. Letter (f) : Drug outlets offering special discounted prices less than 20% of the regular retail prices of drugs shall likewise deduct the percentage difference to make up the total 20% discount as required.
3. Letter (g) : Drug outlets shall mean retail drugstores, hospital pharmacies (government or private) or non-retail outlets for non-prescription drugs.

Adopted: 7 June 1994

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

[*] Initial registration only.

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