Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila

April 18, 2005

**ADMINISTRATIVE ORDER**
No. 2005-0008

**SUBJECT: Policy and Requirements for Availing of Special Permit for Restricted Use of Unregistered Drug and Test Kits for Human Immune Deficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS)**

## I. RATIONALE

The Department of Health - Bureau of Food and Drugs (BFAD) recognizes the need for essential drugs by patients suffering from Human Immune Deficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS). It is likewise accepted that wider and easier access to HIV/AIDS drug products/test kits or Anti-Retroviral (ARV) drug products for these patients is morally, socially and ethically justified in line with the urgent need and effort to control the spread of HIV/AIDS in the country. Access to these drugs at more affordable cost by this vulnerable group of patients, is therefore imperative.

Accordingly, the Department of Health, through the BFAD, in line with their obligation to protect public health and guarantee access to essential drugs for HIV/AIDS patients, shall provide for Special Permit for Restricted Use of HIV/AIDS Drugs/Test Kits and/or ARV Drugs when the conditions and requirements specified hereunder exist and are duly complied with.

## II. SCOPE/COVERAGE

The Department of Health, through the BFAD, by the issuance of the Special Permit, shall make available the access to HIV/AIDS drug products/test kits and/or ARV drug products, including pediatric preparation by the Specialized Institution and Specialty Society, as defined hereunder.

## III. DEFINITIONS

1. Specialized Institution (SI) – refers to a legitimate institution, as determined by BFAD, which particularly deals with patients suffering from HIV/AIDS.

2. Specialty Society (SS) – refers to a legitimate organization, as determined by BFAD, which particularly deals with patients suffering from HIV/AIDS.

3. Specialists – refer to medical doctors or practitioners who have specialized training in treating patients with HIV/AIDS and other immunologic or infectious diseases.

## IV. GUIDELINES AND PROCEDURE

A Special Permit for Restricted Use of Unregistered HIV/AIDS Drugs/Test Kits and/or ARV Drugs shall refer to a Special Permit signed by the BFAD Director granting a Specialized Institution (SI) and/or Specialty Society (SS) the privilege to avail of an unregistered HIV/AIDS and/or ARV Drug through the World Health Organization (WHO), United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), Global Drug Fund (GDF), or any legitimate international organization or establishment for patients with specified volume needed and period of use. Provided that, if the Specialized Institution (SI) or Specialty Society (SS) avails of the unregistered HIV/AIDS Drug/Test Kit and/or ARV Drug through the Department of Health, the latter shall be exempted from securing a License to Operate as a requirement to import the unregistered HIV/AIDS Drug/Test Kit and/or ARV Drug.

In order to secure the Special Permit, the following procedure must be followed:

A. A Specialized Institution (SI) or Specialty Society (SS) shall file a request for Special Permit only for patients suffering from HIV/AIDS. The request shall contain the following information:

1. The estimated volume needed and the specific legitimate international organization or establishment through which the unregistered HIV/AIDS Drug/Test Kit and/or ARV Drug may be procured.

2. The unregistered HIV/AIDS Test Kits and reagents to be used in the monitoring response to treatment, if applicable; and

3. The names and addresses of the Specialists qualified and authorized to use the product.

B. Specific Requirements:

1. A written commitment on the part of all authorized Specialists to submit a Clinical Study Report based on its prescribing quantity administered or used, therapeutic or desired effect and any Adverse Reaction Report to the Specialized Institution (SI) or Specialty Society (SS), which shall endorse the same to BFAD, at the end of each calendar year. This Report shall include pediatric preparations of anti-retrovirals.

2. An estimate of the total requirement of the product for one year.

3. A written waiver on the part of the Specialized Institution (SI)/Specialty Society (SS) to hold BFAD free and harmless from any and all actions, liabilities and/or responsibilities against any damage or injury arising from the use of the unregistered HIV/AIDS Drugs/Test Kits and/or ARV Drugs. The written waiver shall be signed by an authorized officer of the Specialized Institution (SI) or Specialty Society (SS).

4. List of patients and quantity of drugs needed by the patients.

C. The Specialized Institution (SI) or Specialty Society (SS) shall provide a stick-on-label on the HIV/AIDS Drugs/Test Kits and/or ARV Drugs that bears the following words: "For Government Use Only".

D. The Special Permit shall be valid for one (1) year after issuance and may be used as often as may be necessary but only up to the limit of the original authorized total requirements for the HIV/AIDS Drugs/Test Kits and/or ARV Drugs. The Special Permit may be renewed, subject to any re-assessment and/or evaluation by BFAD.

E. Notwithstanding the application and issuance/renewal of the Special Permit, the HIV/AIDS Drugs/Test Kits and/or ARV Drugs covered by the Special Permit shall be subject to eventual registration with the BFAD.

## V. SEVERABILITY CLAUSE

If any part, term or provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

## VI. REPEALING CLAUSE

All orders circulars, rules, regulation, or portions thereof, inconsistent with this Order are hereby repealed or modified accordingly. Provided that, nothing in this Order shall be interpreted or construed to prejudice the right of BFAD to exercise its authority granted by existing laws, rules and regulations.

## VII. EFFECTIVITY

This order shall take effect fifteen (15) days after publication in a newspaper of general circulation.

**MANUEL M. DAYRIT, MD, M.Sc.**
Secretary of Health