Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
M a n i l a

November 3, 1992

ADMINISTRATIVE ORDER
No. 4 s. 1992

SUBJECT : **Policy and Requirements for Availing of Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation.**

The Bureau of Food and Drugs (BFAD) recognizes the need for drugs and devices product/preparation which are not registered or are in the process of registration in the Philippines by patients who are terminally or seriously ill. Access to these products for these patients is morally, socially and ethically justified when there is no existing superior alternative therapy that can likely cure or adequately control their conditions.

Therefore, the BFAD shall henceforth provide for a Compassionate Special Permit For Restricted Use of Unregistered Drugs and Devices Product/Preparation when the conditions and requirements specified hereunder exist and are complied with.

A Compassionate Special Permit for Restricted Use of Unregistered Drug and Devices Product shall refer to a special permit signed by the BFAD Director granting a Specialized Institution (SI) and Specialty Society (SS) the privilege to avail of an unregistered drug and device product through a certain licensed establishment for certain kind/type of patients, specific volume and period.

I. A Specialized Institution/Specialty Society shall file a request for CSP only for patients suffering from the following conditions:

1. Acquired Immune Deficiency Syndrome (AIDS)

2. Cancer

3. Life-threatening conditions

The application shall include the estimated volume needed and the licensed drug/device establishment through which the unregistered drug may be procured.

It shall also identify the names and address of the specialists qualified and authorized to use the product.

II. Requirements

1. A written commitment on the part of all the authorized specialists to submit a Clinical Study Report for every patient given the product describing the quantity administered/use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty Society for BFAD, at the end of each year.

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

3. A waiver of BFAD responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution or Specialty Society.

III. The specified drug establishment shall secure clearance to import from BFAD and its applications shall be accompanied by:

a. A certificate that the product is currently registered in the country of origin.

b. A true copy of the CSP issued to the Specialized Institution (SI)/Specialty Society (SS).

IV. A. The SI/SS shall submit the Clinical Study Reports through the drug/device establishment at the end of the year.

B. The drug/device establishment shall be responsible for the submission of the Clinical Study Reports from the SI/SS and the report of the total volume of the drug/device imported for the year.

Failure on its part to submit these reports will be a ground to deny applications of CSP through or using its establishment and/or future applications for import clearances of the unregistered drug/device under a valid CSP.

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

**(Sgd) JUAN M. FLAVIER, M.D., M.P.H.**
Secretary of Health

Date Approved:
11/16/92