Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

COMPASSIONATE SPECIAL PERMIT (CSP) APPLICATION

Who May Avail : Patients, Doctors, Specialized Institutions, Specialized Society, Hospitals, Importers of Pharmaceutical Products

Fees to be Paid : **Name Patient:**
PHP 500.00/patient + LRF
Institutional Use:
PHP 500.00/product + LRF

CHECKLIST OF REQUIREMENTS

Name Patient:

1. Letter of Application Should include the following:
   a. Name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]
   b. Name and age of the patient with a brief medical history
   c. Itemized, detailed description of product [generic name and brand name (if applicable)] with dosage form and strength (Registered from country of origin)
   d. An estimated quantity/ volume needed/ prescribed by doctor
   e. A written commitment on the part of all the authorized specialists to submit a Clinical 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 through the importer for FDA Philippines
   f. A waiver of FDA Philippines 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.
2. Proof of Payment per patient (PHP 500.00 + LRF)
3. Names and addresses of the specialists qualified and authorized to use the product
4. Curriculum vitae of the prescribing doctor
5. Medical Abstract of Patient
6. Prescription

Institutional Use:

1. Letter of Application Should include the following:
   a. Name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]
   b. Itemized, detailed description of product [generic name and brand name (if applicable)] with dosage form and strength (Registered from country of origin)
   c. An estimated quantity/ volume needed
   d. A written commitment on the part of all the authorized specialists to submit a Clinical 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 through the importer for FDA Philippines
   e. A waiver of FDA Philippines 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.

2. Proof of Payment per product (PHP 500.00 + LRF)
3. Reports as prerequisites of renewal of permit
    a. Reconciliation of number/volume of products requested and number used and the corresponding patients
    b. Additional product details – name and address of manufacturer, batch/lot number, expiry date

END