## CENTER FOR DRUG REGULATION AND RESEARCH
## LIST OF REQUIREMENTS FOR COMPASSIONATE SPECIAL PERMIT

### A. Individual Patient Use

| Requirements | Guidelines |
|---|---|
| 1. Letter of Application | Should include the following<br><br>➢ name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]<br>➢ name and age of the patient with a brief medical history<br>➢ itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength and<br>➢ an estimated quantity/ volume needed/prescribed by doctor<br>➢ 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 through the importer for FDA Philippines<br>➢ 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 (P500 + LRF) |
| 3. Names and addresses of the specialists qualified and authorized to use the product | Curriculum vitae of the prescribing doctor |
| 4. Medical Abstract of Patient | |
| 5. Prescription | S-2 Licensed doctor for dangerous drug preparations or drug products containing controlled chemicals |

**B. Institutional Use**

| Requirements | Guidelines |
|---|---|
| 1. Letter of Application | Should include the following<br><br>➢ name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]<br>➢ itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength and<br>➢ an estimated quantity/ volume needed<br>➢ 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 through the importer for FDA Philippines<br>➢ 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 (P500 + LRF) |
| 3. Reports as prerequisites of renewal of permit | ➢ reconciliation of number/volume of products requested and number used and the corresponding patients<br>➢ Additional product details – name and address of manufacturer, batch/lot number |

Notes:

- All documentary requirements must be in PDF format to be submitted to FDAC or at clinicalresearch@fda.gov.ph.
- Guidelines to e-mail submission can be viewed at FDA Circular No. 2020-006-A "Amendment to FDA Circular No. 2020-006 Entitled "Guidance for Applications and Transactions at the Food and Drug Administration in Light of the Community Quarantine Declaration" Issued on 17 March 2020".