



## J. ISSUANCE OF ELECTRONIC COMPASSIONATE SPECIAL PERMIT (eCSP) OF PHARMACEUTICAL PRODUCTS

The CSP is granted to an institution and/ or physician the privilege to avail an unregistered or investigational drug product through a licensed importer for a certain patient suffering from a condition, with specific volume and period of use.

|                               |   |
|-------------------------------|---|
| <b>Center/Office/Division</b> | : Center for Drug Regulation and Research   |
| <b>Classification</b>         | : Simple  |
| <b>Type of Transaction</b>    | : G2B – Government-to-Businesses  |
| <b>Who May Avail</b>          | : Patients, Doctors, Specialized Institutions, Specialized Societies, Hospitals, Department of Health, and Importers of Pharmaceutical Products |
| <b>Fees to be Paid</b>        | : Named Patient:<br>Php 500.00/patient + 1% LRF<br>Institutional Use:<br>Php 500.00/product + 1% LRF  |

| CHECKLIST OF REQUIREMENTS  | WHERE TO SECURE  |
|--|--|
| <p><b>CHECKLIST OF REQUIREMENTS FOR CSP</b></p> <p>Basic Requirements based on the FDA Advisory No. 2021-0842:</p> <p>Named Patient Use:</p> <ol style="list-style-type: none"> <li>1. Accomplished e-Application Form as prescribed by FDA regulations.</li> <li>2. Curriculum vitae of the Prescribing Doctor</li> <li>3. Medical Abstract of the Patient</li> <li>4. Medical Prescription</li> <li>5. Proof of Payment</li> </ol> <p>Institutional Use:</p> <ol style="list-style-type: none"> <li>1. Accomplished e-Application Form as prescribed by FDA regulations.</li> <li>2. Rationale for the Volume Requested</li> <li>3. Proof of other National Regulatory Authority (NRA) approval</li> </ol> | <p>FDA eServices (<a href="http://www.fda.gov.ph">www.fda.gov.ph</a>)</p> <p>Applicant</p> |



|  |  |
|--|--|
| 4. Distribution Agreement                |  |
| 5. Clinical Study Report (if applicable) |  |
| 6. Proof of Payment                      |  |

| CLIENT STEPS   | AGENCY ACTION   | FEES TO BE PAID | PROCESSING TIME | PERSON RESPONSIBLE        |
|--|---|-----------------|-----------------|---------------------------|
| 1. Access the online application portal through ( <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> ) "Applications"   |   | None            |                 |                           |
| 2. Select the "Compassionate Special Permit" and the type of application (Named Patient Use or Institutional Use), then proceed to New Application   |   | None            |                 |                           |
| 3. Click "I have read and accepted the terms and conditions stated on this form". Declining the declaration shall mean forfeiture of the opportunity to proceed with the application   |   | None            |                 |                           |
| 4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements   |   | None            |                 |                           |
| 5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. | <p>1. Pre-assess the completeness and veracity of documents submitted.</p> <p>If complete, Order of Payment will be generated and will be given to the client thru the eService and Email notification.</p> | None            |                 | FDA Evaluator (CRS Staff) |



|   |  |         |                |                        |
|---|--|---------|----------------|------------------------|
|   | If incomplete, the application will not be received and will be returned to the client. Notice of deficiency will be given to the client thru eServices and Email notification.  |         |                |                        |
| 6. Print the Order of Payment form with Reference Number sent through the declared e-mail address   |  | None    |                |                        |
| 7. Pay the assessed fee as per the system generated Order of Payment Form through payment channels prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL, Landbank Link.bizPortal).<br><br>Then, email a copy of the proof of payment to <a href="mailto:clinicalresearch@fda.gov.ph">clinicalresearch@fda.gov.ph</a> and <a href="mailto:cashierposting@fda.gov.ph">cashierposting@fda.gov.ph</a> | 2. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;   | Php 510 |                | FDA Cashier/CRS Staff  |
|   | 3. Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center<br><br>Note: Acknowledgement receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application. | None    |                | FDA Cashier/CRS Staff  |
| 8. Receives acknowledgement receipt through email   | 4. Evaluation, Checking and quality assurance of the information and documents provided  | None    | 3 working days | CRS Staff/ PRSDD Chief |



|   |   |      |                       |
|---|---|------|-----------------------|
|   | 5. Approval of CSP<br><br>If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial | None | CDRR Director         |
| 9. Receive notification and link of CSP for printing. |   |      |                       |
| <b>TOTAL:</b>   |   |      | <b>3 Working days</b> |