I. COMPASSIONATE SPECIAL PERMIT (CSP) OF PHARMACEUTICAL PRODUCTS [MANUAL SUBMISSION]

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.

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

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR CSP	
Name Patient	
1. Letter of Application Should include the following:	
a. name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]	Applicant Company
b. name and age of the patient with a brief medical history	Applicant Company
c. itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength (Registered from country of origin)	Applicant Company
d. an estimated quantity/ volume needed/prescribed by doctor	Applicant Company
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	Applicant Company/Authorized Specialists

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 (P500 + 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 Note: In case the product is an Investigational Product, the applicant should submit a copy of the Clinical trial registry of an on-going phase 3 clinical trial where the same drug product is being used in the treatment of the target indication.	Applicant Company Applicant Company Applicant Company Prescribing Doctor Prescribing Doctor Prescribing Doctor
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 c. 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 d. 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 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	Applicant Company Applicant Company Applicant Company Applicant Company/Authorized Specialist Applicant Company Applicant Company Applicant Company Applicant Company

Note: In case the product is an Investigational Product, the applicant should submit a copy of the Clinical trial registry of an on-going phase 3 clinical trial where the same drug product is being used in the treatment of the target indication.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for pre-assessment clinicalresearch@fda.gov.ph For COVID-19 related applications, sends through clinicalresearch@fda.gov.ph	1. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	2. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	3. Endorses the received application to the Center (applications which satisfactorily passed the pre-assessment).	None	Day 1 1 working day	FDAC *Personnel*

	4. Receives the application from FDAC and encodes/updates the database	None	Day 2 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	5. Decks/Assigns the application to the assigned evaluator	None	Day 2 1 working day	CDRR Director/ CRR Unit
	6. Evaluates the application according to requirements and prescribed standards	None	Day 2 1 working day	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/FDRO III (Senior*
	7. Reviews the evaluated application bearing the recommendation of the Evaluator	None	Day 2 1 working day	Clinical Research Section *Supervisor*
	8. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	Day 2 1 working day	*FDRO I/II/III*
	9. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 2 1 working day (per batch of applications)	PRSDD *Chief*

	10. Signs and approves the final decision	None	Day 2 1 working day (per batch of applications)	CDRR *Director*
	11. Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	Day 3 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
3. Receives the permit or final response	12. Releases the permit or final response to the client	None	Day 3 1 working day	AFS Releasing Section Personnel
	TOTAL:		**3 Working days**	