13. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS INITIAL – MEDICAL GRADE OXYGEN)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Medical Gases which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Medical Grade Oxygen
Fees to be Paid	:	**Initial Branded:** Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF MEDICAL GRADE OXYGEN	
1. Notarized Integrated Application Form (in excel and in pdf format)	FDA Website
2. Proof of payment (based on AO 50 s. 2001)	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/ Manufacturer
4. Technical Specifications of Finished Product	

5. Certificate of Analysis (CA) of Finished Product 6. Certificate of Analysis issued by CIGI for the product 7. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls 8. Complete quality control procedures for the finished product. 9. Philippine Standard Quality Certification Mark issued by the Bureau of Product Standards, Department of Trade and Industry 10. Labeling Materials (facsimile) 11. For imported products: Foreign GMP Clearance 12. Copy of valid License to Operate	Applicant Company/ Manufacturer Applicant Company/ Manufacturer CIGI Applicant Company/ Manufacturer Applicant Company/ Manufacturer Bureau of Product Standards, Department of Trade and Industry Applicant Company/Manufacturer FDA CDRR FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC.	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. 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	None		CDRR *Personnel*

3. 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.	3. 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*
	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. Queuing time of the application before decking to evaluators	None	Day 3-11 9 working days	
	6. Decks/Assigns the application to the assigned evaluator	None	Day 12 1 working day	LRD *Chief*
	7. Evaluates the application according to requirements and prescribed standards	None	Day 13-35 23 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the	Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended	None	Day 36 1 working day	*FDRO I/II/III*
	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E- NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 37-48 12 working	*FDRO III*
	9. Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	Day 49 1 working day	*FDRO I/II*

	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		*FDRO III*
	11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 50-52 3 working days (per batch of applications)	*FDRO IV (Supervisor)*
	12. Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	Day 53-55 3 working days (per batch of applications)	*LRD Chief*
	13. Signs and approves the final decision	None	Day 56 1 working day (per batch of applications)	*CDRR Director*
	14. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 57 1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	15. Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	Day 58-59 2 working days (per batch of applications)	*CDRR-Records Personnel*
4. Receives the CPR/LOD/letter	16. Releases the CPR/LOD/letter to the client	None	Day 60 1 working day	*AFS Releasing Section Personnel*

TOTAL:	**60 working days**
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 60 working days was proposed instead of 180 working days).	