



## P. PRODUCT CLASSIFICATION

The Product Classification is granted to Marketing Authorization Holder in order to identify if the product is classified as a drug, medical device, food supplement or cosmetics or non-registrable in FDA.

<b>Center/Office/Division</b>	: Center for Drug Regulation and Research
<b>Classification</b>	: Highly Technical
<b>Type of Transaction</b>	: G2B – Government-to-Businesses
<b>Who May Avail</b>	: All licensed establishments
<b>Fees to be Paid</b>	: AO 50 s. 2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Product Classification Requirements 1. Letter of intent 2. Complete Technical Profile of the Product, shall include the following: - description, formulation/list of ingredients with corresponding amount per unit dose, indication, direction for use, claims (if any), labelling materials/brochures 3. Classification of the product in the country of origin 4. List of countries where the product is currently marketed and the corresponding classification of the product 5. Representative sample 6. Proof of Payment	Applicant Company

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 <i>Personnel</i>



<p>2. E-mail submission: Submits the application for pre-assessment through <a href="mailto:fdac.letters.cdrr@fda.gov.ph">fdac.letters.cdrr@fda.gov.ph</a></p>	<p>3. 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).</p>	None		CDRR <i>Personnel</i>
<p>3. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl  Sends proof of payment to the FDAC.</p>	<p>4. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.</p>	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC <i>Personnel</i>
	<p>5. Receives the application from FDAC and encodes/ updates the database</p>	None	Day <u>2</u> <u>1</u> working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	<p>6. Decks/Assigns the application to the assigned evaluator</p>	None	Day <u>2</u> <u>1</u> working day	CDRR <i>Director/ CRR Unit Personnel</i>



<p>If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator</p>	<p>7. Evaluates the application according to requirements and prescribed standards</p> <p>*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication</p>	<p>None</p>	<p>Day <u>3-15</u> <u>13</u> working days</p>	<p><i>Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)</i></p>
	<p>8. Reviews the evaluated application bearing the recommendation of the evaluator</p>	<p>None</p>	<p>Day <u>16-17</u> <u>2</u> working days</p>	<p><i>Clinical Research Section Supervisor</i></p>
	<p>9. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief</p>	<p>None</p>	<p>Day <u>17</u> <u>1</u> working day</p>	<p><i>FDRO I/II/III</i></p>
	<p>10. Checks and recommends the decision of the evaluator/s by affixing initial/signature</p>	<p>None</p>	<p>Day <u>18</u> <u>1</u> working day (per batch of applications)</p>	<p><i>PRSDD Chief</i></p>
	<p>11. Signs and approves the final decision</p>	<p>None</p>	<p>Day <u>19</u> <u>1</u> working day (per batch of applications)</p>	<p><i>CDRR Director</i></p>
	<p>12. Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section</p>	<p>None</p>	<p>Day <u>20</u> <u>1</u> working day (per batch of applications)</p>	<p><i>CDRR-CRR Unit Personnel</i></p>



4. Receives the letter	13. Releases the letter to the client	None	Day <u>20</u> <u>1</u> working day	AFS Releasing Section Personnel
<b>TOTAL:</b>		<b>PHP 510.00</b>	<b>20 working days</b>	