



## O. SALES PROMO PERMIT OF PHARMACEUTICAL PRODUCTS (INITIAL AND AMENDMENT)

This permit is issued to concerned parties for the conduct of their sales promotion activities of applicable drug products.

<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 Manufacturers, Distributors, Importers, Exporters, Wholesalers, Traders, and Retailers of Pharmaceutical Products
<b>Fees to be Paid</b>	: In accordance to DTI-DOH JAO NO. 1 s. 2000 Prescribing a Schedule of Fees and Charges for Sales Promotion Activities  <b>Initial:</b> Sales promotions – the permit fees for the conduct of sales promotion schemes shall be as follows: Coverage: (Fees) NCR only or in several regions in NCR and Nationwide: Php 1,000 + 1% LRF More than one (1) region in NCR and Nationwide: Php 750 + 1% LRF Several provinces/cities/municipalities within a single region: Php 500 + 1% LRF Single province/city/municipality: Php 250 + 1% LRF  The amount of fees for sales promotions (except for discount scheme type of promotion) which includes variables covered by blanket approval (covering a period of one (1) year as prescribed by the Consumer Act) shall be in accordance with the enumerated hereunder or in accordance with geographical areas, whichever is higher:  Amount of Prices: (Fees) Up to Php 50,000 : Php 250 + 1% LRF Php 50,000 - Php 150,000. : Php 500 + 1% LRF Php 150,000 - below Php 300,000.: Php 1,000 + 1% LRF  Php 300, 001 -Php 500,000 : Php 2,000 + 1% LRF Php 500,001 - Php 1,000,000 : Php 3,000 + 1% LRF Above Php 1,000.000 : Php 5,000 + 1% LRF  <b>Amendment:</b> Php 310



CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
<p><b>CHECKLIST OF REQUIREMENTS FOR SALES PROMO PERMIT</b></p> <p><b>INITIAL</b></p> <ol style="list-style-type: none"> <li>1. Accomplished Integrated Application Form</li> <li>2. Letter of Intent for application of Promo Permit</li> <li>3. List of Participating Products in Excel Format (Sheet 3 of Information Sheet)</li> <li>4. Copy of the valid product notification/registration/ exemption</li> <li>5. Information Sheet and Mechanics of the Sales Promotion</li> <li>6. Layout of Promo materials (if applicable)</li> <li>7. Proof of payment</li> <li>8. Self-Assessment Form for Sales Promo Permit</li> </ol> <p><b>AMENDMENT</b></p> <ol style="list-style-type: none"> <li>1. Accomplished Integrated Application Form</li> <li>2. Letter of Intent specifying the type of amendment</li> <li>3. Copy of previously issued valid promo permit</li> <li>4. Supporting documents for the requested amendment</li> <li>5. Proof of payment</li> <li>6. Self-Assessment Form for Sales Promo Permit</li> </ol>	<p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p> <p>Applicant Company</p>

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.pacd.cdrr@fda.gov.ph">fdac.pacd.cdrr@fda.gov.ph</a></p>	<p>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 (DTN).</p>	None		<i>CDRR Personnel</i>
<p>3. For accepted applications, pays the required fee through any of the following:</p> <ul style="list-style-type: none"> <li>• BANCNET</li> <li>• Landbank OnColl</li> <li>• Landbank Link.bizPortal</li> </ul> <p>Sends proof of payment to the FDAC.</p>	<p>3. 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 <i>FDAC Personnel</i>
	<p>4. 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>5. Decks/Assigns the application to the assigned evaluator</p>	None	Day <u>3</u> <u>1</u> working day	<i>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>6. Evaluates the application according to requirements and prescribed standards</p> <p><i>*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication</i></p>	<p>None</p>	<p>Day <u>4-13</u> <u>10</u> working days</p>	<p><i>Food-Drug Regulation Officer (FDRO) /II (Junior Evaluator)</i></p>
	<p>7. Prints the final response and transmittal, and forwards it to the Senior Evaluator</p>	<p>None</p>	<p>Day <u>14</u> <u>1</u> working day</p>	
	<p>8. Reviews the evaluated application bearing the recommendation of the junior evaluator and forwards the application to the Product Research and Standards Development Division (PRSDD) Chief</p>	<p>None</p>	<p>Day <u>15-16</u> <u>2</u> working days</p>	<p>FDRO III (Senior Evaluator)</p>
	<p>9. Checks and recommends the decision of the senior evaluator/s by affixing initial/signature</p>		<p>Day <u>17</u> 1 working day (per batch of applications)</p>	<p>PRSDD Chief</p>
	<p>10. Signs and approves the final decision</p>	<p>None</p>	<p>Day <u>18</u> 1 working day (per batch of applications)</p>	<p>CDRR Director</p>
	<p>11. Encodes/Updates the Database and endorses the final response to the AFS Releasing Section</p>	<p>None</p>	<p>Day <u>19</u> 1 working day (per batch of applications)</p>	<p>CDRR-CRR Unit Personnel</p>
<p>4. Receives the final response (sales promo permit or letter of disapproval)</p>	<p>12. Releases the final response to the client (sales promo permit or letter of disapproval)</p>	<p>None</p>	<p>Day <u>20</u> 1 working day</p>	<p>AFS Releasing Section Personnel</p>
<p><b>TOTAL:</b></p>			<p><b>20 working days</b></p>	