



23. ACKNOWLEDGEMENT TO MINOR VARIATION-NOTIFICATION APPLICATIONS

This acknowledgment is issued to any minor changes to a registered pharmaceutical finished product classified as minor-variation notification.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Refer to FDA Circular No. 2014-008, Annex D Payment shall be on a per product, per change basis Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf Refer to FDA Circular No. 2014-008, Annex D Payment shall be on a per product, per change basis Regular PACs: Php500.00 + LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
FDA Circular No. 2014-008-A 1. Hard copy: a. Two (2) copies of notarized Annex B (see attached sample Annex B); b. Original copy of the Official Receipt. 2. Soft copy: a. Notarized latest Annex C; b. Portable document format (PDF) copy of signed integrated application form (IAF); c. IAF in Microsoft Excel format; d. Scanned copy of Certificate of Product Registration (CPR) and/or proof of renewal;	Applicant company/ Manufacturer FDA Cashier Applicant Company/ Manufacturer



<p>e. For Certificate of Listing of Identical Drug Product (CLIDP), a copy of Principal CPR (PCPR) variation approval (where applicable);</p> <p>f. Complete documentary requirements based on the ASEAN Variation Guidelines, FDA Circular No. 2014-008, FDA Circular No. 2014-008-A, and FDA Circular No. 2016-017 and pertinent evidence supporting change/s</p>	
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CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
<p>1. E-mail submission: Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph</p>	<p>1. Receives the application and forwards the application to CD RR pre-assessor</p>	<p>None</p>		<p>FDAC Personnel</p>
	<p>2. Pre-assesses the completeness of the application.</p> <p>If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment.</p> <p>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>	<p>None</p>		<p>CD RR Personnel</p>



<p>2. Submits application with complete documents and requirements through fdac.letters.cdrr@fda.gov.ph</p> <p>If the application is incomplete or incorrect, DO NOT receive the application.</p>	<p>3. Accepts the application with complete and correct requirements.</p> <p>Assigns Document Tracking Number (DTN) and issues pre-assessment slip to the applicant indicating to proceed to payment</p>	None	Day 1 1 working day	<i>FDAC Personnel</i>
<p>4. Pays the required fee through any of the following:</p> <ul style="list-style-type: none"> • BANCNET • Landbank OnColl • Landbank Link.bizPortal <p>Upon payment, the applicant shall send the copy of the Official Receipt to the FDAC through email.</p>		See Table Above	Day 1 1 working day	<i>FDA Cashier/ Landbank</i>
	<p>4. Endorses the received applications (soft/hard copies) to the Center, including the soft copy of transmittal for post-acknowledgement</p>	None		<i>FDAC Personnel</i>
	<p>5. Acknowledges the notification, encodes and updates the database and Document Tracking System status</p>	None	Day 1 1 working day	<i>CDRR-CRR Personnel</i>
Service covered under FDA Circular No.2020-026.		TOTAL:	1 working day	

Note: Day 1 strictly refers to Tuesdays and Wednesdays which are the Notification days following FDA Circular No. 2014-008-A.