

Product Name: \_\_\_\_\_

DTN: \_\_\_\_\_

## SELF-ASSESSMENT CHECKLIST FOR VARIATION APPLICATION OF ACTIVE INGREDIENT REGISTRATION

*Note: Please check only the variation applied and applicable requirements.*

DOCUMENTARY REQUIREMENTS	YES	NO	Remarks	FDA's Use Only
<b>A. MAJOR VARIATION</b>				
<b>1. Change in GHS Category/ hazard class</b>				
1.1. Completely accomplished Integrated Application Form				
1.2. Letter of request				
1.3. Copy of valid LTO				
1.4. Copy of the valid original CPR				
1.5. Copy of SDS				
1.6. Copy of complete toxicity studies, if request is for change in hazard class				
1.7. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
<b>B. MINOR VARIATIONS</b>				
<b>1. Change in business name of the manufacturer/ distributor</b>				
1.1 Completely accomplished Integrated Application Form				
1.2 Letter of request				
1.3 Copy of valid LTO reflecting the variation				
1.4 Copy of the valid original CPR				
1.5 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
<b>2. Change of address of the distributor of the product</b>				
2.1. Completely accomplished Integrated Application Form				
2.2. Letter of request				
2.3. Copy of valid LTO reflecting the new address				
2.4. Copy of the valid original CPR				
2.5. Any valid document/s showing proof of transfer				
2.6. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
<b>3. Addition or deletion of packaging of the product</b>				
3.1. Completely accomplished Integrated Application Form				
3.2. Letter of request				
3.3. Copy of valid LTO reflecting the new address				
3.4. Copy of the valid original CPR				

3.5. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
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--- To be filled out by CCHUHSRR Personnel ---

<b>Evaluator:</b>		<b>Signature:</b>	
<b>Position:</b>		<b>Date:</b>	
<b>Decision:</b>	<input type="checkbox"/> Acceptance <input type="checkbox"/> Non-acceptance	<b>Remarks:</b>	