

Product Name: _____

DTN: _____

SELF-ASSESSMENT CHECKLIST FOR VARIATION APPLICATION OF HOUSEHOLD/URBAN PESTICIDE REGISTRATION

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

DOCUMENTARY REQUIREMENTS	YES	NO	Remarks	FDA's Use Only
A. MAJOR VARIATIONS				
1. Change in product name (brand name/variant name)				
1.1 Completely accomplished Integrated Application Form				
1.2 Letter of request				
1.3 Duly notarized affidavit/ declaration of no change in the formulation				
1.4 Copy of valid LTO				
1.5 Copy of the valid original CPR				
1.6 Extension of use or claim and new bio-efficacy study*, if there is request to include additional target pests.				
*Bio-efficacy test protocol pre-approval for studies conducted on 01 Oct 2023 onwards				
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				
2. Change in rate, timing or frequency of application or method of application				
2.1 Completely accomplished Integrated Application Form				
2.2 Letter of Request				
2.3 Copy of valid LTO				
2.4 Copy of the valid original CPR				
2.5 Extension of use or claim and new bio-efficacy study*, if there is request to include additional target pests.				
2.6 Study or studies* that shall justify request for change in rate, timing or frequency of application, or method of application				
*Bio-efficacy test protocol pre-approval for studies conducted on 01 Oct 2023 onwards				
2.7 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
3. Change in label claim/ Request for additional target pest(s)				
3.1 Completely accomplished Integrated Application Form				
3.2 Letter of request				
3.3 Copy of valid LTO				
3.4 Copy of the valid original CPR				

3.5 Extension of use or claim and new bio-efficacy study*, if there is request to include additional target pests.				
*Bio-efficacy test protocol pre-approval for studies conducted on 01 Oct 2023 onwards				
3.6 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
4. Change in GHS Category/ hazard class				
4.1 Completely accomplished Integrated Application Form				
4.2 Letter of request				
4.3 Copy of valid LTO				
4.4 Copy of the valid original CPR				
4.5 Copy of SDS				
4.6 Copy of complete toxicity studies, if request is for change in hazard class				
4.7 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
B. MINOR VARIATIONS				
1. Change in business name of the manufacturer/ distributor				
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				
2. Change in product ownership				
2.1. Completely accomplished Integrated Application Form				
2.2. Letter of request				
2.3. Copy of valid LTO reflecting the variation				
2.4. Copy of the valid original CPR				
2.5. Copy of Termination Contract/ Deed of Assignment				
2.6. Copy of the Agreement of the new MAH and manufacturer				
2.7. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
3. Change of address of the distributor of the product				
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. Any valid document/s showing proof of transfer				
3.6. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				
4. Addition or deletion of packaging of the product				
4.1. Completely accomplished Integrated Application Form				
4.2. Letter of request				
4.3. Duly notarized affidavit/declaration of no change in the formulation				
4.4. Copy of valid LTO reflecting the new address				
4.5. Copy of the valid original CPR				
4.6. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable				

--- To be filled out by CCHUHSRR Personnel ---

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