



Application form for Variation for Registered cosmetic, vector control product and public health laboratory chemical product

1. Administrative information	
1.1	Particulars of Applicant/Registrant Company name..... Physical address..... Postal address..... Country..... Telephone..... Telefax..... E-mail.....
1.2.	Particulars of the Manufacturer Name:..... Physical address:..... Postal address..... Country..... Telephone..... E-mail.....
1.3	Particulars of Local Technical Representative/distributor (if applicable): Name..... Physical address..... Postal address..... Country..... Telephone..... E-mail.....
2. Finished Product (FP)	
	Registration Certificate Number:..... Brand Name:..... Active Ingredient and strength:..... Date of Market Authorization issuance:..... Registered pack size and packaging material:..... Registered shelf life:.....

	Registered storing condition:..... Intended use:.....
3. Application details	
3.1	Variation Type: (tick applicable option) Minor Variation: Major Variation:
3.2	Summary of proposed variation
3.2.1	Current product details:
3.2.2	Proposed product new details:
3.2.3	Reason for change:
4. Variation type: (tick all applicable options)	
4.1	Minor variation (Justification summary):
4.2	Major variation (Justification summary):
5. Submission checklist	

	<input type="checkbox"/> Application letter/Cover letter <input type="checkbox"/> Copy of the existing Market Authorization <input type="checkbox"/> Appointment letter of the LTR <input type="checkbox"/> Letter of acceptance from the proposed LTR and a copy of termination notice of the previous LTR (where applicable) <input type="checkbox"/> List of affected products with their registration numbers <input type="checkbox"/> A copy of manufacturing/premise license (where applicable) <input type="checkbox"/> Revised Artwork label (where applicable)
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6. Declaration

Please check all declarations that apply. I

declare that:

- For each change all conditions as stipulated in the Rwanda FDA Guidelines for variation application of registered medicated cosmetic, cleaning chemical, household pesticide and laboratory chemical product for the change requested are fulfilled.
- There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.
- The information submitted is true and correct.

Name: _____ Title/Designation _____

Signature: _____ Date: _____