1014	ANNEX D				
1015	5 Procedure in the Submission of Variation LTO Application				
1016					
1017	A. Procedure outline				
1018					
1019	1. Accessing and navigating the FDA eServices Portal System				
1020	2. Filing an application				
1021	a Page 1: Declaration & Undertaking				
1022	h Page 2: License to Operate				
1023	c Page 3: Contact Information				
1023	d Page 4: Type of Variation				
1024	e Page 5: Self-Assessment Review				
1025	e. Tage 5. Sen-Assessment Review				
1020	B Step-by-step procedure				
1027	Follow the steps outlined below in order to submit a variation cosmetic I TO application				
1020	Follow the steps outlined below in order to sublint a variation cosmetic ETO application.				
1029	1 Accessing and navigating the EDA aConvised Dantal System				
1050	1. Accessing and having the FDA eservices Fortal System A_{access} the online nortal through (https://acamvia.com/da/acumh/) and aliak				
1021	a. Access the online portal through (https://eservices.ida.gov.ph/) and chek "Applications" found on the upper right corner of the eServices lending page				
1052	Applications found on the upper right corner of the eservices failding page.				
1033	Files econology Fortial Hom I Applications				
1034 1035					
1035	Home				
1030					
1037	osed)//ces				
1038	AUTHORIZATION				
1039					
1040					
1041	APPROVED				
1042					
1043	To guarantee the safety, quality, purity, efficacy of products in order to				
1044	protect and promote the right to health of the general public.				
1045	VISION The Food and Drug Administration to be an internationally recognized				
1046	center of excellence in health product regulation by 2026.				
1047					
1048	b. Click the License to Operate for Cosmetic and Type of Establishment (Distributor,				
1049	Trader, Manufacturer, Packer or Repacker)				
1050					
1051	eServices Portal Home Applications				
1052					
1053	Home / Applications				
1054	Applications				
1055					
1056					
1057					
1058					
1059					
1060	License to Operate Certificate of Product Registration Compassionate Special Permit Authorization permits for health establishments Marketing Authorization for Health Products Permits granted to individuals or institutions to have				
1061	access to investigational or unregistered drug products				
1062					
1063					
1064					

Home / Applications / License to Operate

License to Operate Drug **Bottled Water** Food For establishments that handle bottled water products For establishments that handle drug For establishments that handle food products products lodized Salt Device Cosmetic or establishments that handle salt For establishmer device products nts that handle For establishm nts that handle roducte smetic products Household/Urban Pesticide Household/Urban Hazardous Substances Toy and Child Care Article For establishments that handle Household/Urban pesticide products For establishments that handle Toy and Child Care Article products For establishments that handle Household/Urban Hazardous Substances products **Application Status** Distributor Trader Check the current status of your License authorization for distributor License authorization for trader application establishments establishments Manufacturer Packer Repacker License authorization for License authorization for packer License authorization for repacker manufacturer establishments establishments establishments

- i. Select the primary activity the applicant intends to engage in which may be one of the following:
 - **Manufacturer** An establishment that is engaged in any and all operations involved in the production of cosmetic products including preparation, processing, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
 - **Packer** An establishment that packages bulk cosmetic product into its immediate container with the end view of storage, distribution, or sale of the product.
- **Repacker** An establishment that repacks a finished product into smaller quantities in a separate container and/or into secondary packaging, including but

view of storage, distribution, or sale of the product. 1116 1117 Trader- An establishment which is a registered owner of a cosmetic product • and procures the raw materials and packing components, and provides the 1118 production monographs, quality control standards and procedures, but 1119 1120 subcontracts the manufacture of such product to a licensed manufacturer. 1121 Distributor- Any establishment that imports/exports raw materials, active • 1122 ingredients and/or cosmetic products for its own use or for wholesale distribution to other establishments or outlets. If the distributor sell to the general 1123 1124 public, it shall be considered a retailer. 1125 1126 c. Click the Variation Application. 1127 Home Applications Downloadables FAQs eServices Portal 1128 1129 Home / Applications / License to Operate / Huhs / Manufacturer 1130 1131 Household/Urban Hazardous Substances Manufacturer 1132 1133 1134 1135 1136 1137 1138 Initial Renewal Variations 1139 Renew existing License to Operate Apply for a new License to Operate Apply for changes in the existing 1140 License to Operate 1141 1142 1143 2. Filing an application 1144 1145 a. Page 1: Declaration & Undertaking To start the application, read carefully and agree to the declaration & undertaking 1146 form. Make sure to check the box found below and click on "Start Application". 1147 1148 eServices Portal 1149 1150 Home / Applications / License to Operate / Cosmetic / Manufacturer / Variations 1151 Cosmetic Manufacturer Variations 1152 1153 Declaration & Undertaking Declaration & Undertaking 1154 I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing 2 License to Operate 1155 1156 3 Contact Information records, legal documents and available information 1157 I, likewise declares, undertakes and agrees that: 1158 4 Variations • I. The said establishment shall be open during its business hours under the of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times 1159 II. The pharmacist/s and the other appropriate allied health professionals, upon and 5 Self-Assessment Review during employment in the establishment, is/are not and will not in any 1160 connected to, employed by or engaged with any other FDA-regulated establishment; • III. The approved and valid License to Operate shall be displayed in a conspicuous 1161 place in the establishment visible to my customers 1162 • IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusinaly similar name 1163 I agree to the declaration and undertaking 1164 Start Application 1165

not limited to relabeling, stickering, and bundling for promo packs with the end

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1166					
1167					
1168	b. Page 2: License to Operate				
1169	Provide the existing LTO Number, Validity Date, and Security Code (by scanning				
1170	the QR Code from the	he given docu	ment). Please ensure the correctness of the data		
1171	given to proceed with	n the change in	licensing authorization. Tick "I'm not a robot"		
1172	then click "Next" to	proceed.			
1173	\sim				
1174	eServices Portal		Home Applications Downloadables FAQs		
1175					
1176	Home / Applications / License to	o Operate / Cosmetic /	Manufacturer / Variations		
1177	Cosmetic Manufa	cturer Varia	tions		
1170					
1180	Declaration & Undertaking	License to Ope	rate		
1181		* License Number	License Number		
1182		* Date of Validity	Date of Validity		
1183	3 Contact Information	* Security Code	Security Code		
1184	-		Please scan the QR Code in the document. For previously issued LTO, enter the sequence		
1185	4 Variations				
1186			l'm not a robot		
1187	5 Self-Assessment Review		reCAPTCHA Privacy - Terms		
1188			Back Next		
1189					
1190					
1191					
1192	c. Page 3: Contact Info	ormation			
1193	Provide an updated c	ontact informa	ation if applicable. Click "Next" to proceed.		
1194					
1195	eServices Portal		Home Applications Downloadables FAQs		
1196	Home / Applications / License	to Operate / Cosmetic / I	rader / Variations		
1197	Nome / Applications / Leense		ruder / vunutiona		
1190	Cosmetic Trader	Variations			
1200		0			
1200	Declaration & Undertaking	Contact Informa	ation		
1201		* Email Address			
1202	License to Operate		The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to		
1203	3 Contact Information		the declared email address		
1205	-		Update mobile number if necessary		
1205	4 Minor Variations	Landline Number	Landline Number		
1207			Update landline number if necessary		
1208	5 Self-Assessment Review		Back Next		

d. Page 4: Variations

- i. Choose and tick the box of the type of variation/s applicable for your LTO. More than one type of cosmetic LTO variation can be applied simultaneously in a single application.
- Upload the required document/s for the variation/s in accordance to FDA Circular No. 2013-002, FDA Circular No. 2013-002-A and DOH AO 2020-0017, in pdf format by clicking "Upload Files", then click "Next"

	eServices Portal Home Applications Downloadables FAQs					
	Home / Applications / License to Operate / Cosmetic / Trader / Variations					
	Cosmetic Trader Variations					
	Declaration & Undertaking Minor Variations					
1217	License to Operate If there is also a change in warehouse address, You should also apply it by ticking the Change of Warehouse Variation.					
1218	Contact Information Transfer of Office Location					
	Minor Variations Transfer/Addition of Warehouse					
	Change of Ownership Change of Business Name Change of Business Name					
1222	Self-Assessment review Zonal Change in Office Address Change of Qualified Personnel					
1223	Change of Authorized Person					
1224	Bock Next					
1226						
1227	e. Page 5: Self-Assessment Review					
1228	i. A Self-Assessment Review summary will appear that reflects all the declare					
1229	information and uploaded documents.					
1230	11. Review and recheck the information declared and documents uploaded. If there are corrections to be made, the information and documents can directly be					
1231	undated on the Self-Assessment Review page					
1233	iii. After the self-assessment review, the applicant shall confirm the correctness of					
1234	the data and uploaded documents. Tick "I'm not a robot", Data Privacy Act					
1235	declaration and click the "Confirm" submit the application.					
1236	iv. Auto-generated electronic email will be sent containing the Application					
1237	Summary					
1230	eServices Portal Home Applications Downloadables FAQs					
1240	Cosmetic Trader Variations					
1241	Declaration & Undertaking Self-Assessment Review					
1242	2 License to Operate					
1243	Contact Information License Number CCHUHSRR-NCR-CT-0635					
1244	Minor Variations Security Code					
1245	Self-Assessment Review					
1247	Contact Information					
1248	* Email Address The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for lass of					
1249	Access to the declared email address Mobile Number					
1250	Landline Number Landline Number I necessary Landline Number Landline Number I necessary Update landline number If necessary					
	General Information					
	Type of Application Variation Primary Activity Trader					
	* Additional Activities Exporter of Own Products, Importer of Raw Materials for Own Use, Wh					
	I'm not a robot					
	I hereby confirm that all information I have provided are true and correct to the best of my knowledge.					
	I understand that any errors that I have commited in this online form may be considered grounds for refusal or cancellation of my application.					
	In compliance to the Data Privacy Act 2012, I give consent to use any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.					
	Back Confirm					