

National Pharmaceutical Regulatory Agency Ministry of Health Malaysia

USER MANUAL

QUEST 3+ System

Module: **COSMETIC NOTIFICATION** (Front-End)

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INTRODUCTION

This user manual will serve to guide the applicants from the industry to conduct transactions in QUEST 3+ for:

- 1. Application / Registration / Renewal / Withdrawal / Changes for Cosmetic Notification Products / Variances
- 2. Application / Registration New Certificate Of Free Sale
- 3. Application / Registration New Market Sampling Registered/Unregistered User
- 4. Application / Registration New In House Evaluation Registered/Unregistered Use

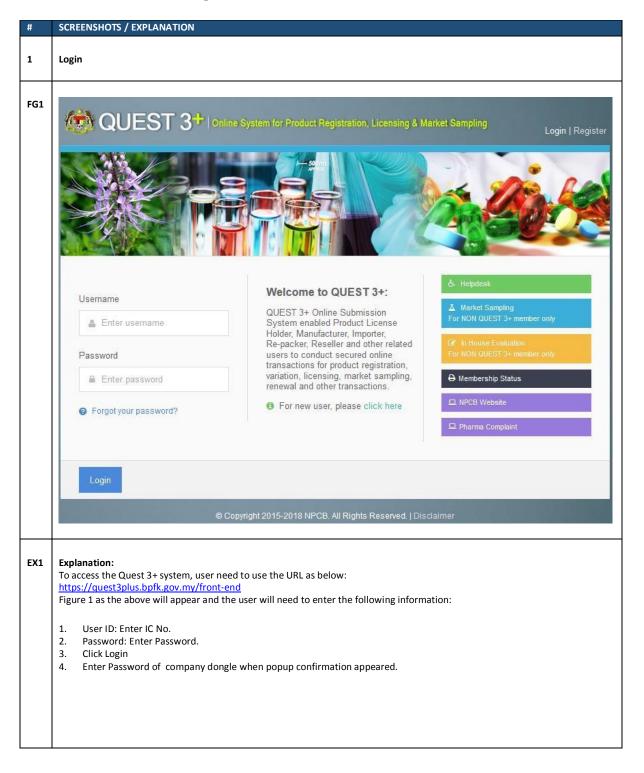
Pre-requisite:

The application / registration process by the applicants will be conducted completely online including payments. The following are the pre-requisites before conducting the transactions in QUEST 3+:

- 1. Internet Ready PC
- 2. Broadband Internet connection
- 3. Internet Explorer 9.0 and above
- 4. Valid Digital Certificate (USB Token) To be purchased online during Membership Application
- 5. Scanner
- 6. PDF Reader/Writer Software
- 7. Photo editor to edit (crop, resize or other editing functions) your attachments in jpg format
- 8. Valid email account for correspondences and system notifications
- 9. Online banking account (Personal or Business) or credit card to conduct payment transactions via FPX (Financial Process Exchange). FPX is a payment channel that allows you to make payment via online real-time through your current or savings account. All you need is an Internet banking account with any of FPX participating banks.

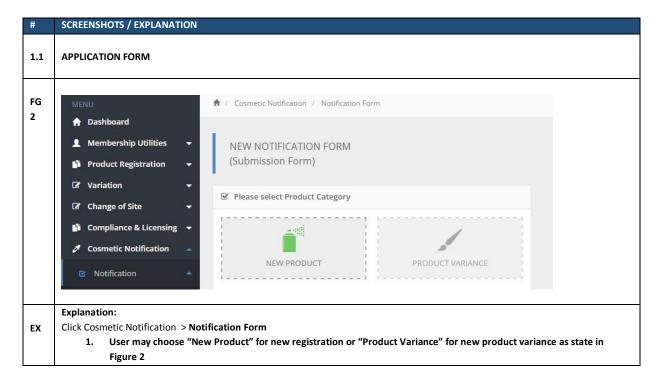


QUEST3+ Front-end login

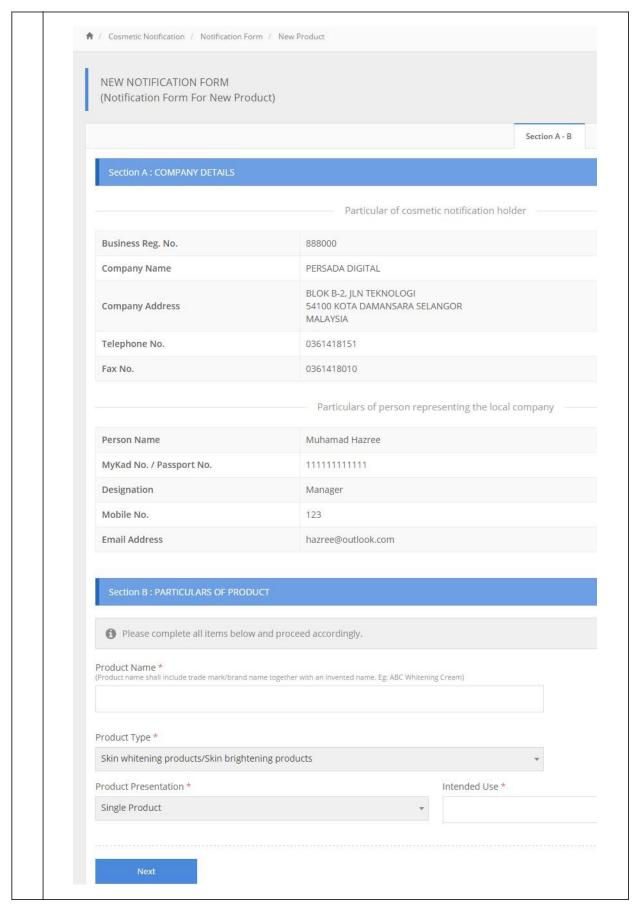




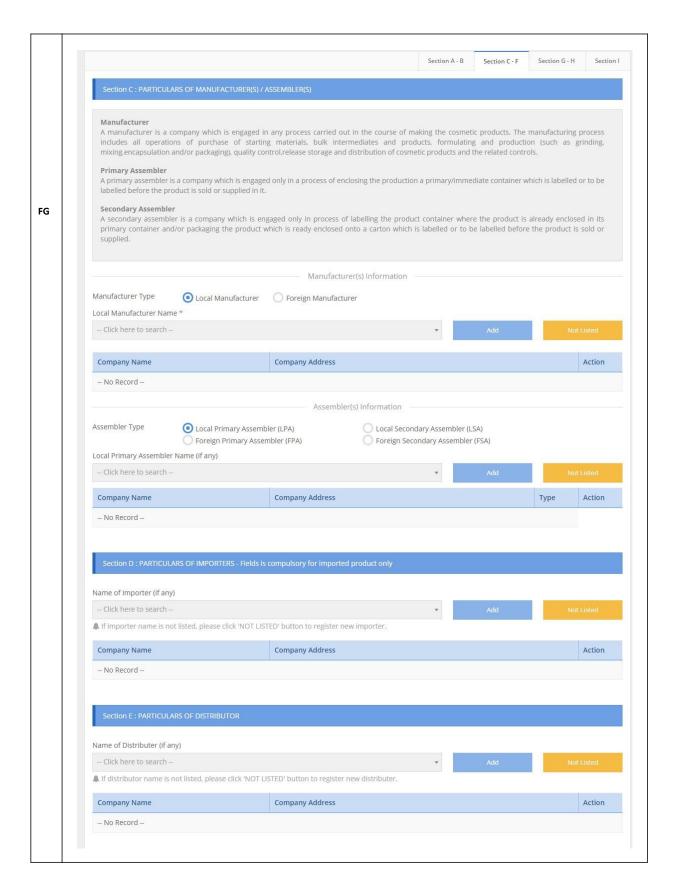
1.0 NOTIFICATION



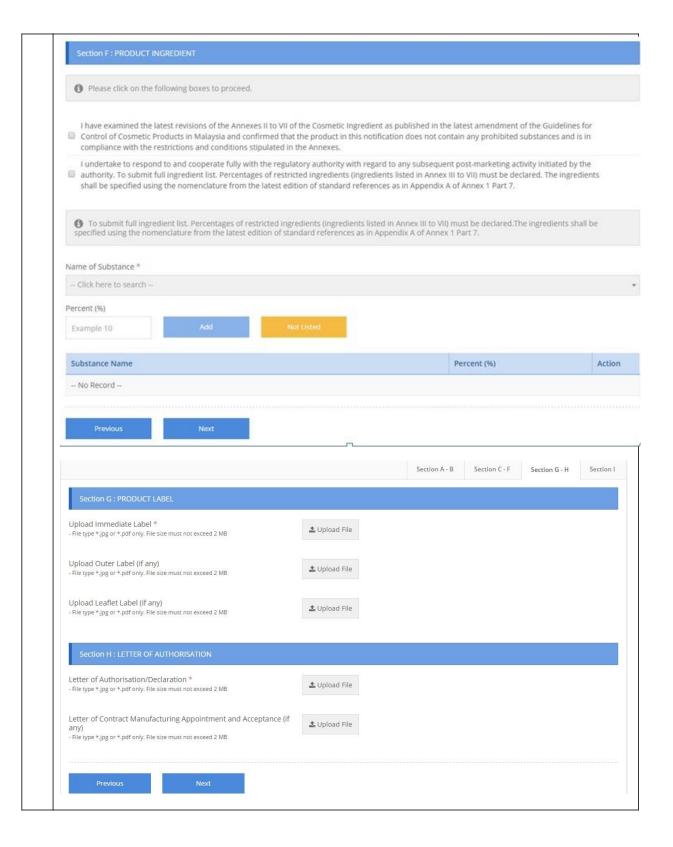














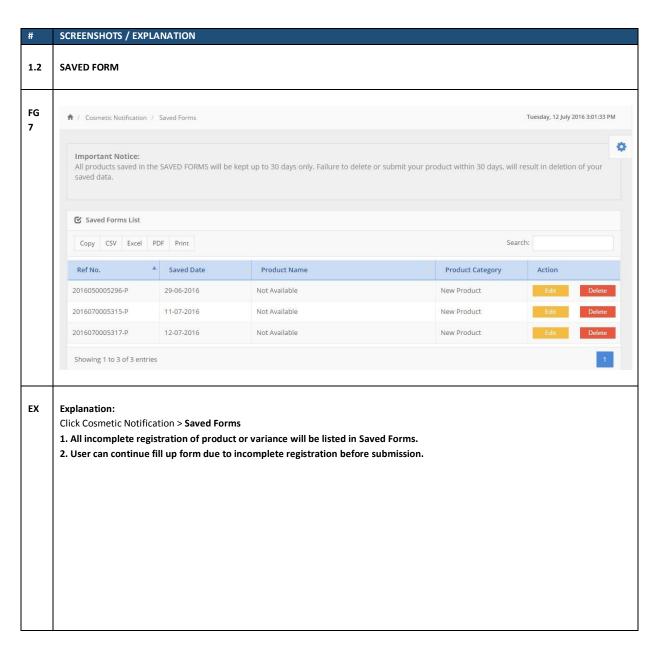
1. I hereby declare on behalf of my company that the product in the notification meets all the requirement of the Guidelines for Control of Cosmetic Products in Malaysia, its Annexes and Appendices, which have been transposed into local legislation. 1. Ensure that the products technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes; 2. Notify the Authority of fatal or life threatening serious adverse event (1) as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge; 3. Complete the Adverse Cosmetic Event Report Form (2) within 8 calendar days from the date of my notification to the Authority in para 2(2) above, and to provide any other information as may be requested by the Authority; 4. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible as possible and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report From; 5. Notify the Authority of any change in the particulars submitted in this notification; 6. Ensure that if and when directed by the Authority I will recall the product from the market, and discontinue selling or supplying the product; 3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies; 4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all standards and specifications of the product that I have declared to the Authority; 5. I understand that I cannot place reliance on the acceptance of my product notification by the Authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority; As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products. Set out in Appendix 1 to the Guide Manual of the Industry on Adverse Event Reporting of Cosmetics Products. Click SUBMIT once you have completed the notification form and ready for submission. Incomplete form will be saved in Saved Forms.
 Completed submission pending for payment will be saved in Payment. I have read and agree to the above declaration. O Submission of Notification Thank you for using QUEST 3+ Application Service Your reference no is: 2016070005329-P To make immediate payment, please select payment method below. If you want to PAY LATER or to make a bulk payment, please proceed to Payment menu VIA PERSONAL ACCOUNT



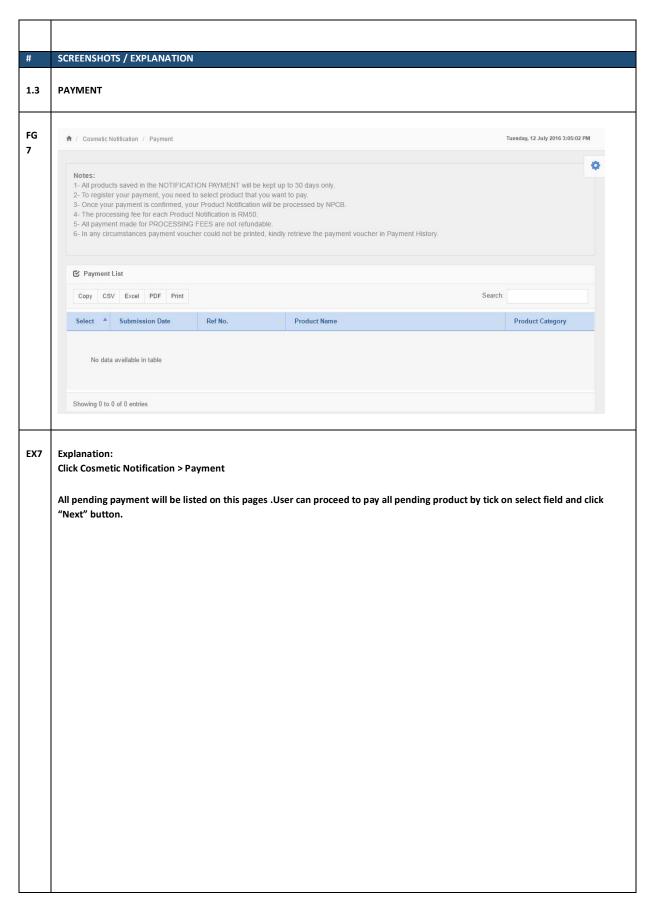
Explaination

ΕX

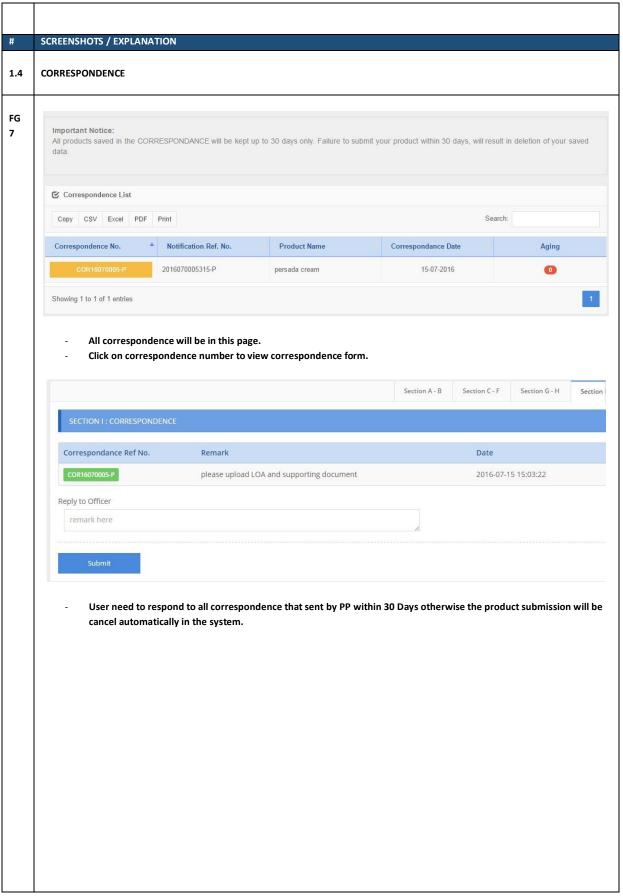
- 1. Users must fill out the Notification form in which the fields marked * are mandatory. Details are as follows
 - SECTION B: Product name is mandatory field
 - SECTION B: Intended Use is mandatory field
 - SECTION F: Checkbox 1 is mandatory field
 - SECTION F: Checkbox 2 is mandatory field
 - SECTION I: Checkbox 1 is mandatory field
 - SECTION C: Please add at least one manufacturer
 - SECTION F: Please add at least one subtance
 - SECTION G: Upload Immediate Label is mandatory field
 - SECTION H: Letter of Authorization/Declaration is mandatory field
 - User need to make a payment for complete their product registration. If user choose to pay after registration, user can choose between 3 type of payment as above figure. Otherwise user just click on "Payment Menu" for pay later.



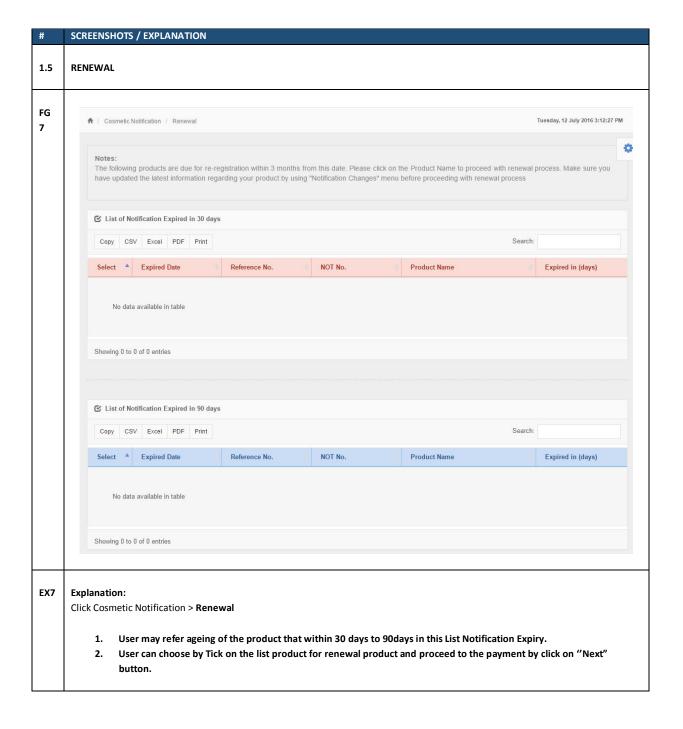




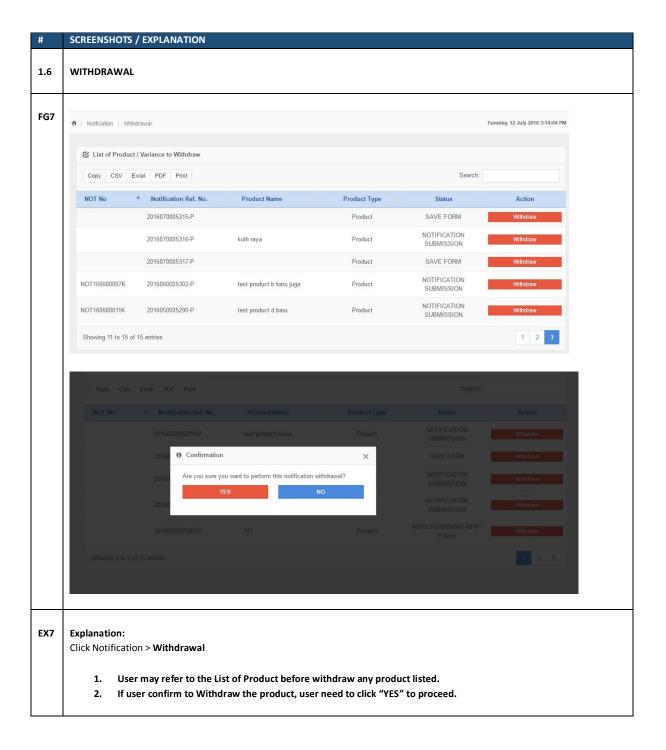




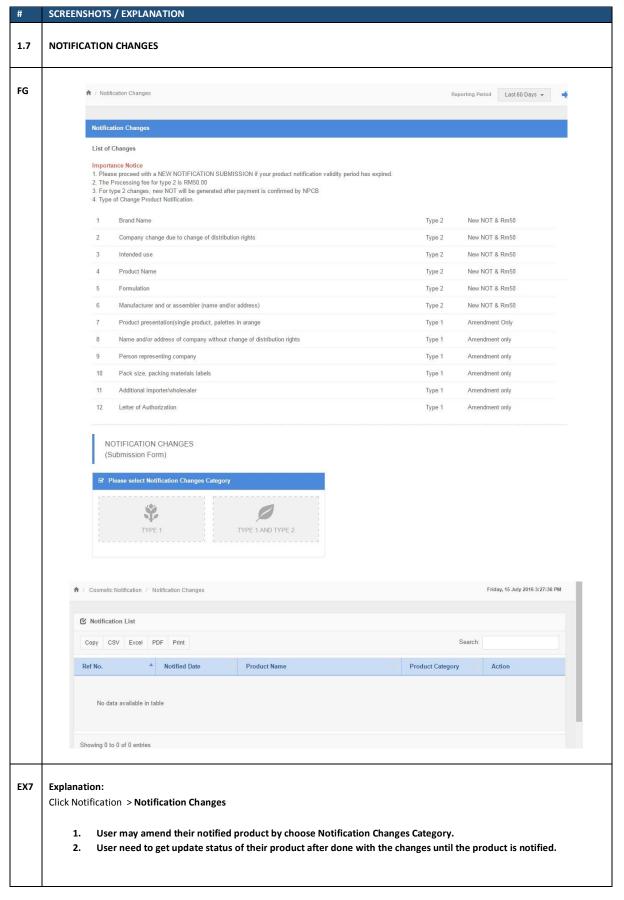












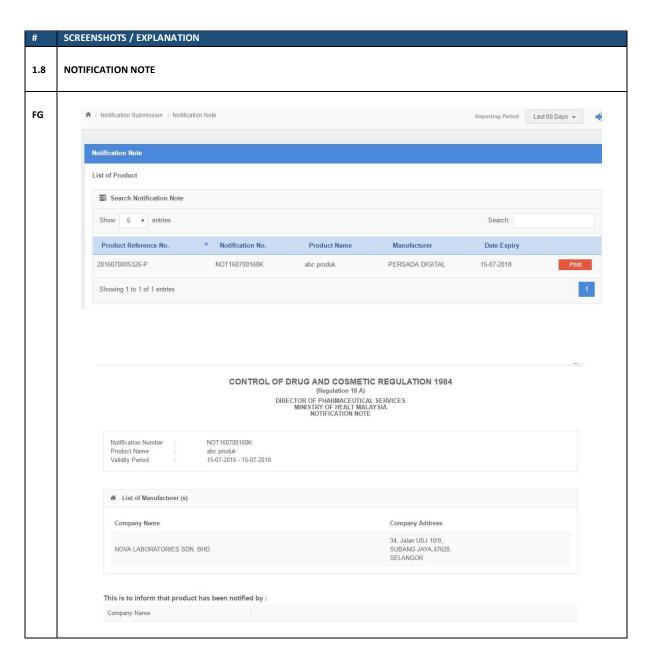


TYPE 1 (WITHOUT PAYMENT)

- Product presentation(single product, palettes in arrange
- Name and/or address of company without change of distribution rights
- Person representing company
- Pack size, packing materials labels
- Additional importer/wholesaler
- Letter of Authorization

TYPE 2 (RM50)

- Brand Name
- Company change due to change of distribution rights
- Intended use
- Product Name
- Formulation
- Manufacturer and or assembler (name and/or address)





EX7

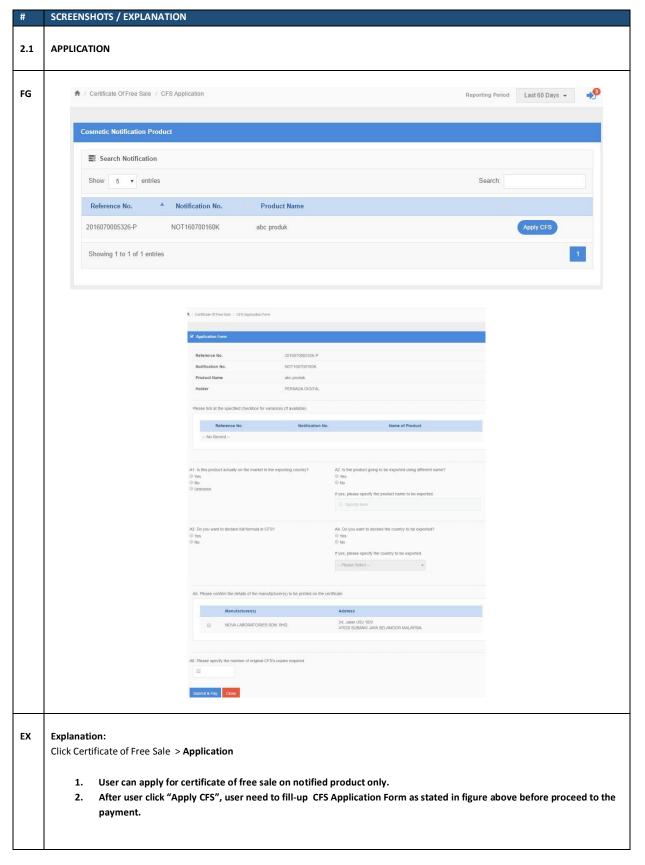
Explanation:

Click Notification > Notification Note

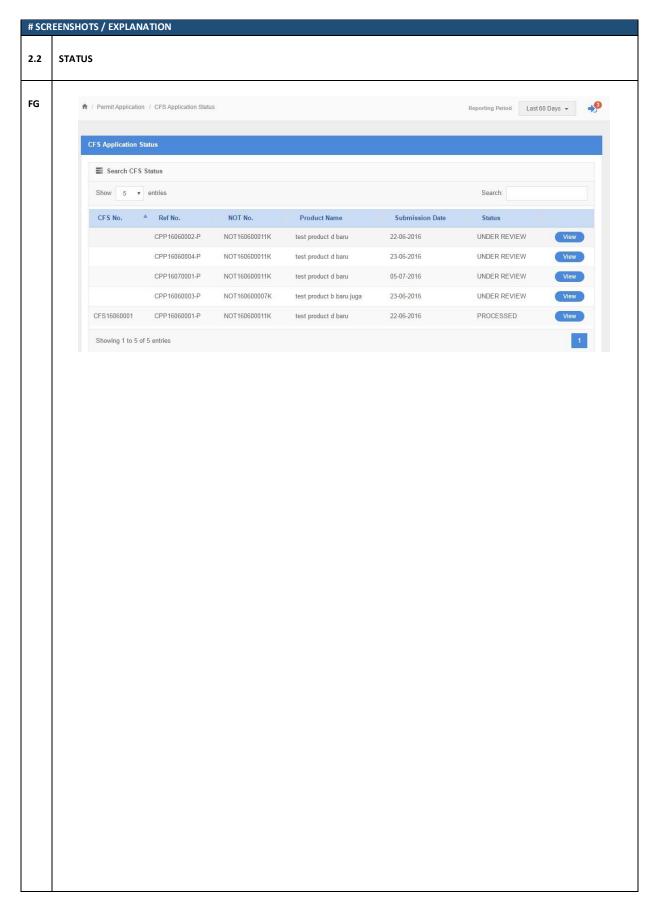
- 1. All notified product will appear in this Notification Note.
- 2. User can print their notification note by clicking "PRINT".



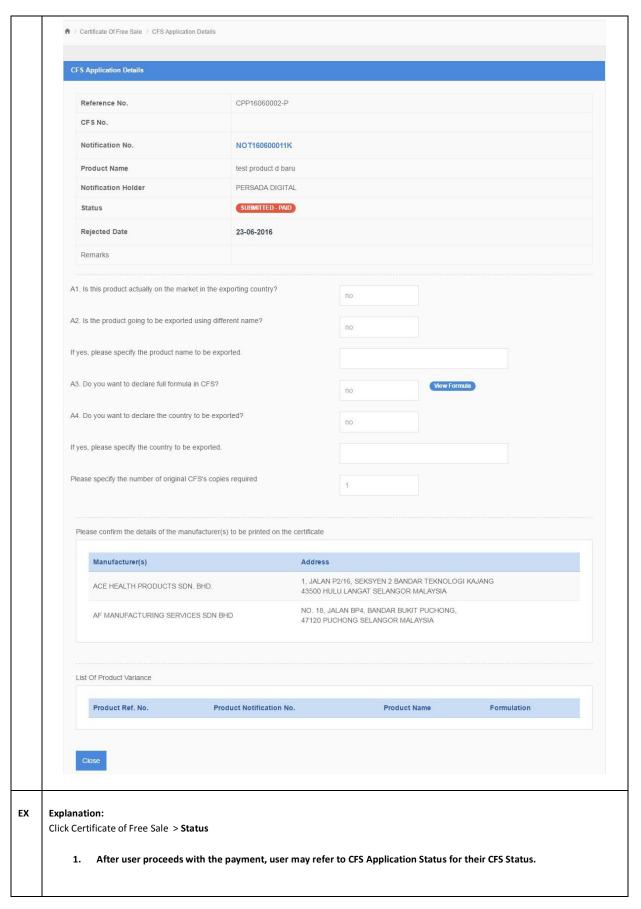
2.0 CERTIFICATE OF FREE SALE



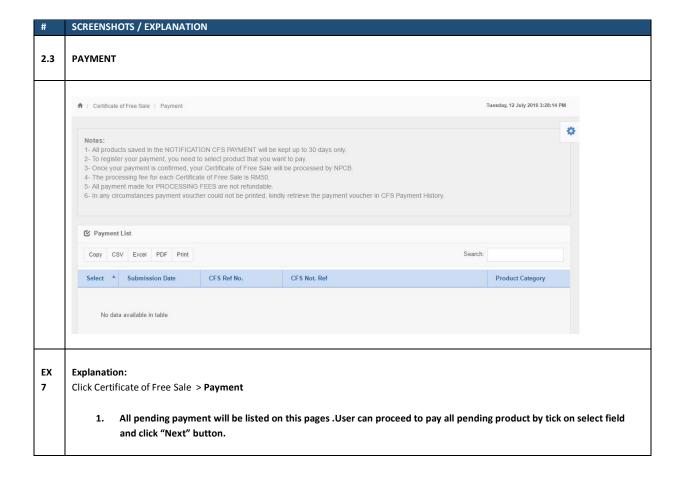




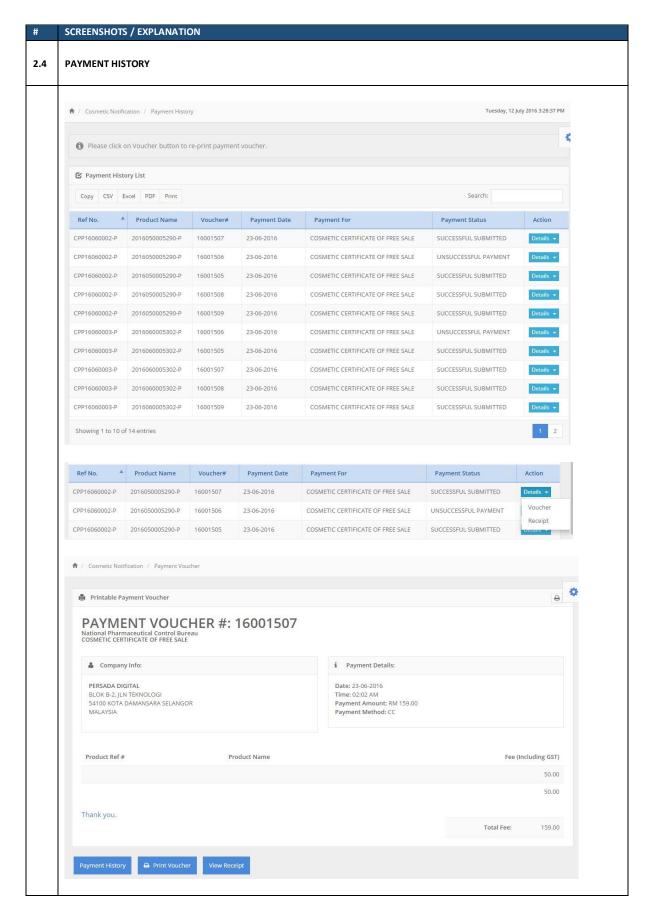




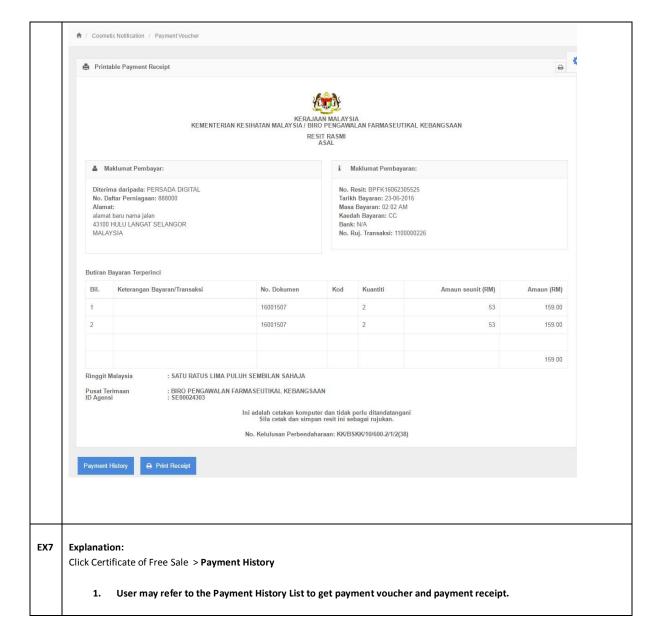






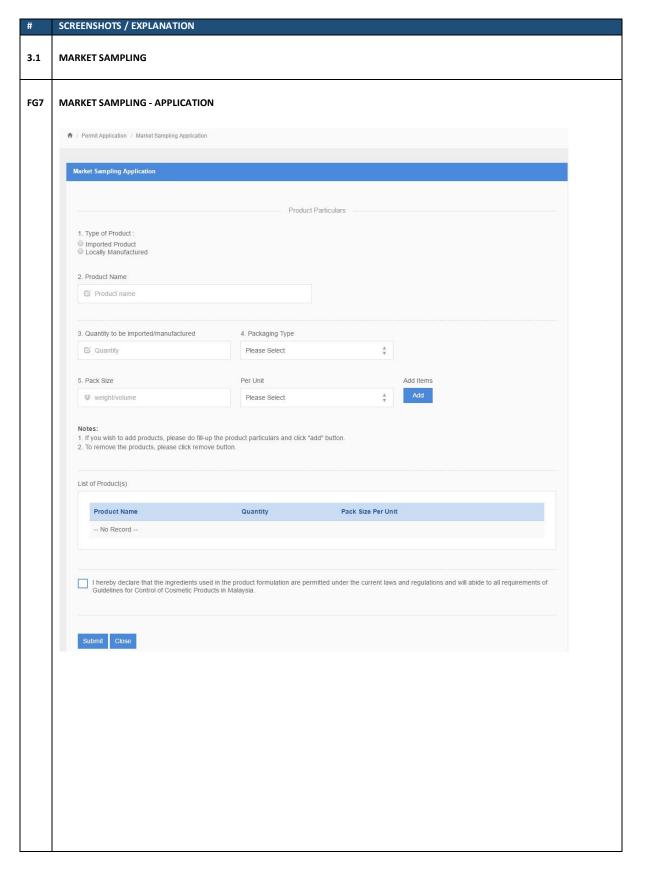




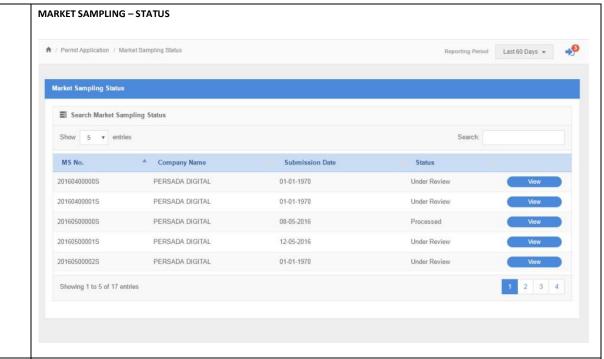




3.0 PERMIT APPLICATION





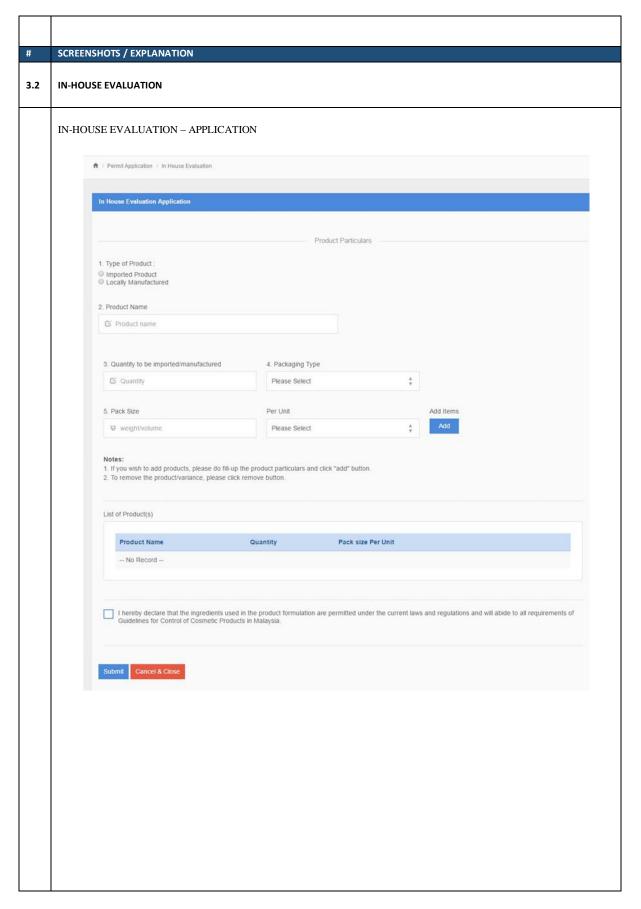


EX7 Explanation:

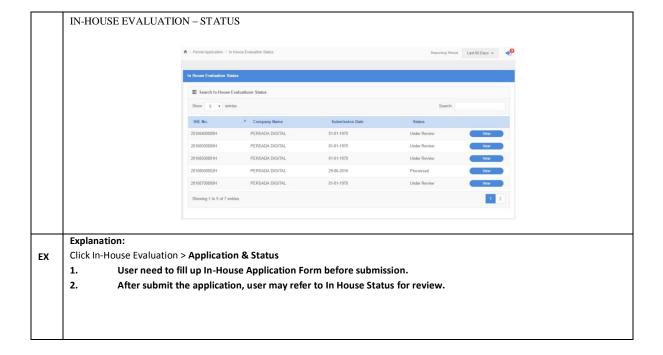
Click Permit Application > Market Sampling

- 1. User need to fill up Market Sampling Application Form before submission.
- 2. After submit the application, user may refer to Market Sampling Status for review.



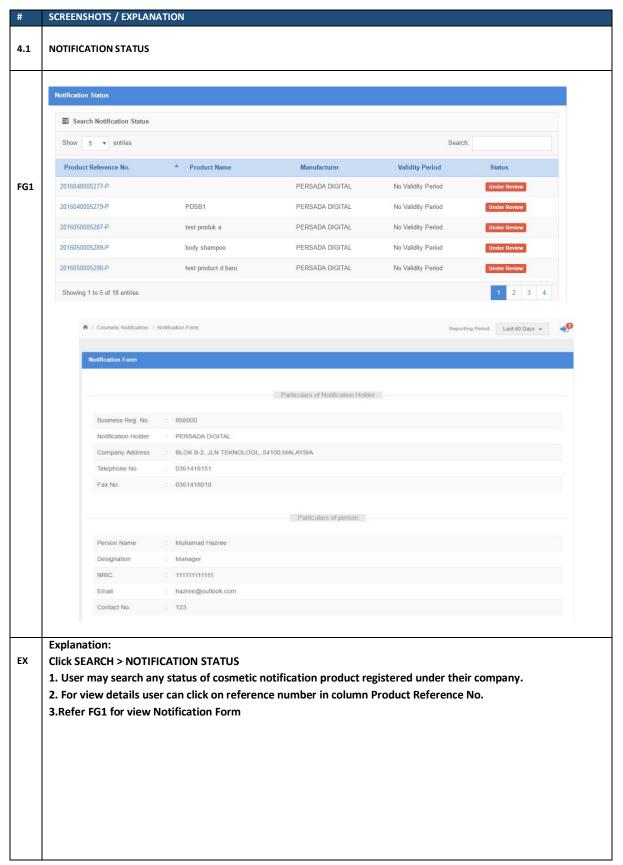




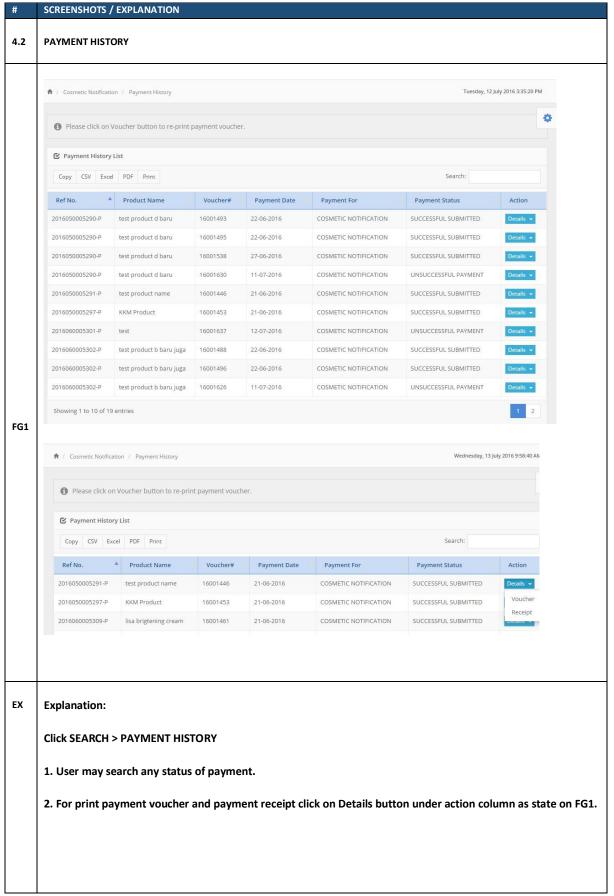




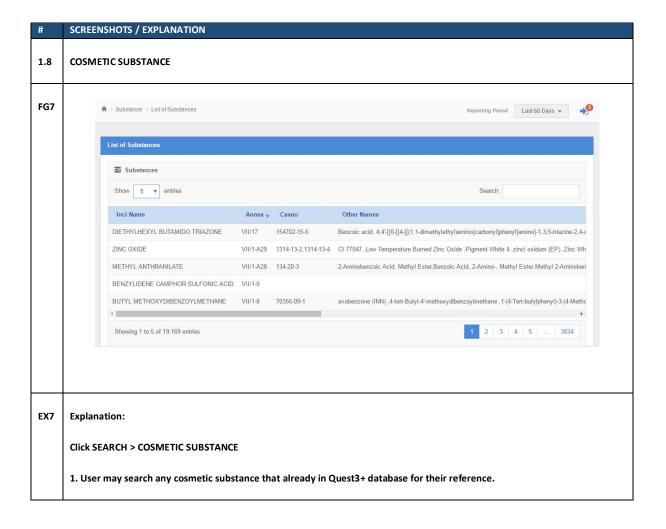
4.0 SEARCH





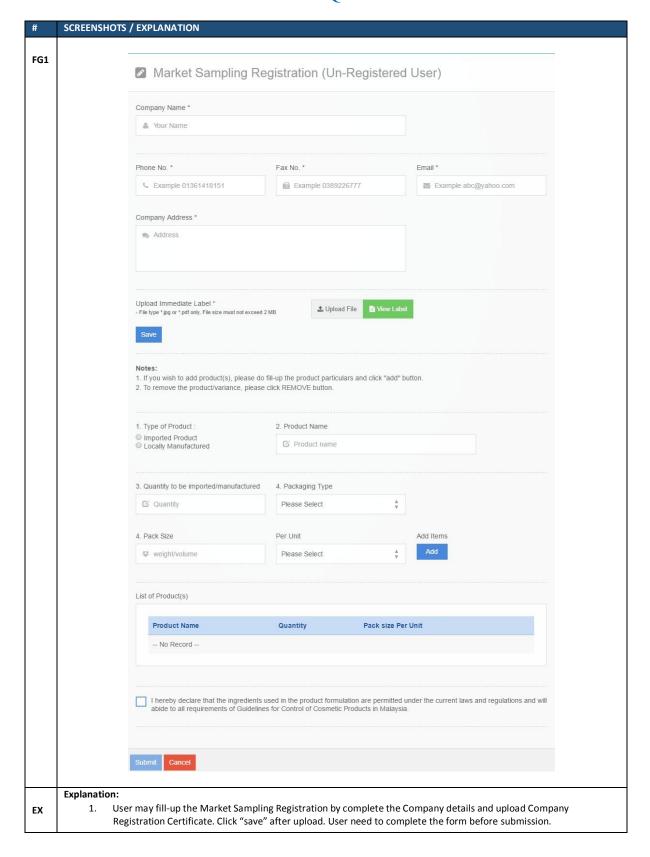








5.0 MARKET SAMPLING FOR NON QUEST 3+ MEMBER ONLY





6.0 IN HOUSE EVALUATION FOR NON QUEST 3+ MEMBER ONLY

