



## MEDICAL DEVICE FIELD CORRECTIVE ACTION

General information	
Subject	Incorrect expiry dates on the barcode label on bundled pack
Date	16 March 2017
Product Details	
Product	ReNu® Fresh™ Multi-purpose Solution (bundled pack)
Brand name	ReNU®
Packing	1. Twin Pack of 355ml + 60ml x 5 2. Twin Pack of 355ml + 60ml x 2
Lot Number	1. 16F14818, 16F15018 & 17F00418 2. 17F00318
Problem description	
Description	Incorrect expiry (YYYY-MM) printed on the barcode stickers which were affixed on the bundled product. The actual expiry remains visible from the carton and bottle label.
Health Risk	No identified health risk to users.
Actions Required	
Retailers' Action	<ol style="list-style-type: none"> <li>1. Review your inventory and hold all unused units for the affected lots. See below an example of a product label for ease in identifying the lot number.</li> </ol> <div style="display: flex; align-items: center; justify-content: center;">  <div style="border: 1px solid black; padding: 5px; margin-left: 20px;"> <p>RenuFeshTP 355ml+60ml*5Guardian</p>  <p>4 891768 112984 SKU - SG623282G012 Lot : 16F14818 Exp : 2018-08</p> </div> </div> <ol style="list-style-type: none"> <li>2. Complete the enclosed Acknowledgement Form and return to Bausch &amp; Lomb within 5 working days. Bausch + Lomb representative will arrange for a pickup of the identified product.</li> <li>3. Should there be any queries from end-users about expiry dates of the affected lots, please advise your customers to refer to the expiry dates printed on the cartons or the bottle label or direct the enquiry to our customer service (see below).</li> </ol>

Our Contact	
Customer Service	Tel: 1800 278 1421 Email: Esther.Tan@bausch.com
Regulatory Affairs	Khor Cherng Yeh Email: <a href="mailto:ch.khor@inovapharma.com">ch.khor@inovapharma.com</a> Tel: 60 3 7680 8821

Our Customer Service or Regulatory teams are able to provide you with additional information and/or guidelines if necessary.

We greatly appreciate your understanding and prompt assistance, and apologize for any inconvenience this may have caused.

Sincerely,

**GRACE GUANG**  
**MANAGING DIRECTOR**  
**BAUSCH & LOMB (SINGAPORE) PRIVATE LIMITED**

**Guardian Health & Beauty**  
Storage Distribution Centre  
21 Tampines North Drive 2  
Singapore 528765

### **Acknowledgement Form**

This is to acknowledge receipt of the above referenced Field Corrective Action notification dated March 16, 2017.

**Product Details:**

***ReNu® Fresh™ Multi-purpose Solution (bundled pack)***

**Please confirm inventory levels of the affected product at your facility:**

Product	Lot #	# Received (pack)	# Used	# in inventory/to be returned
Renu Fresh Twin Pack of 355ml + Renu Fresh 60mlx5	16F14818	1,800		
	16F15018	1,300		
	17F00418	1,742		

Further advice: ☐ credit note required ☐ stock replacement required

Remark: \_\_\_\_\_

I hereby certify that I have quarantined the above listed product to prevent use and am awaiting pick up by a Bausch + Lomb representative or agent.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Company Stamp

\_\_\_\_\_  
Signature

**Please complete, sign and return this form to Bausch & Lomb representative, or**

**Fax: (65) 6725 8010**

**Email: [Esther.Tan@bausch.com](mailto:Esther.Tan@bausch.com)**