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Date: 24-May-2021
To: **Saudi FDA**
Country: **Kingdom of Saudi Arabia**

URGENT FIELD SAFETY NOTICE
Voluntary Medical Device Product Recall of certain Lots

Impacted Products:

1. Biotrue® Multi-purpose Solution,
2. ReNu® MultiPlus Multi-Purpose Solution,

Legal Manufacturer: Bausch + Lomb Incorporated,
1400 North Goodman Street, Rochester, NY 14609, USA
Manufacturing Site: Bausch + Lomb - Iom Spa,
Via Pasubio 34, Macherio, Monza Brianza, 20846, Italy.

Dear Sir/ Madame,
After compliments,

This is to inform you of a medical device voluntary product recall involving Biotrue® Multi-purpose Solution and ReNu® MultiPlus Multi-Purpose Solution.

Description of Issue:

Kindly be informed that we, Bausch + Lomb, the Legal Manufacturer of the products listed above, were notified by one of its third party suppliers in Milan, Italy which sterilizes some packaging components (i.e. bottles, plugs, and caps but not the actual contents/solution itself), for our contact lens solutions, eye wash and eye lubricant product, as well as associated private label brands prior to manufacturing in our facility in Milan, Italy, of a compliance issue with its sterilization process. Bausch + Lomb is one of many companies impacted by this situation. Consequently, this voluntary recall will be conducted as a precautionary measure.

Investigation/Outcome:

As a result of the investigation and considering that the sterilization process of the packaging components at the supplier cannot be fully confirmed, we are conducting a voluntary recall of certain lots of Biotrue® contact lens solution, ReNu® MPS Multi-purpose solution, Boston® Simplus Multi-action contact lens solution, Sensitive Eyes® contact lens solution, EasySept® contact lens solution, Ophtaxia® eye wash solution, Sensitive Eyes® eye lubricant solution and associated private label brands that were manufactured in our Milan, Italy facility. A complete list of the Bausch + Lomb products and lots impacted by this recall **in KSA** is outlined in Table A on Page No. 5.

Consumer Safety Risks:

The health and safety of everyone who uses our products is our utmost priority. While there is a low risk of infection with these products, we have chosen to voluntarily recall these certain lots of products because we cannot confirm the supplier's conformance to process compliance requirements for some of the components of these products. No serious adverse events have been reported to date in association with this issue.

We are committed to ensuring that all our products meet the highest standards of quality and take matters such as this very seriously. Consequently, this additional precautionary field action to recall specific impacted lots at the **CONSUMER** level is necessary.

Appropriate regulatory bodies are being informed of this action. Additionally, details regarding this recall are included in this document, therefore, no further information will be distributed.

Field Safety Action Plan:

Stage 1 (Distributor, Wholesaler and Retailer Level)

1. The following Field Action Plan will be deployed with our Authorized Business Partner:
   a. The Authorized Distributor will examine their inventory to identify any remaining stock from the Product/ Lots mentioned in Table A (Page No. 5). Such quantities should have been previously quarantined at their site based on the issued hold alerts notification for the identified impacted lots and recorded on the enclosed Annex No. 1 (Distributor Acknowledgment/ Reply Form) and return to the email address : customerservicedwc@bauschhealth.com **within 5 business days from receipt of this letter.**
   b. The Authorized Distributor will generate Sales History Report (Sales tracking report by Batch) for the impacted Lots including Customer Name and address, SKU, Lot No. and Quantity sold. Such report will be sent to the email address: customerservicedwc@bauschhealth.com.
   c. Utilizing Annex No. 2 (Wholesaler/ Retailer Acknowledgment/ Reply Form), the Authorized Distributor will send it to all the identified businesses as per their Sales History Report. This activity shall be completed within **7 business days from receipt of this letter.**
   d. The Wholesaler/Retailer shall identify the remaining stock of the impacted Product/Lots, complete Annex No. 2 (Wholesaler/ Retailer Acknowledgment/ Reply Form) and return it to the Authorized Distributor within **15 business days from receipt of this letter.**
   e. The Authorized Distributor shall coordinate the return process of the identified stock from the impacted Product/Lots from the Wholesaler/ Retailer and reconcile with the previously identified quarantined quantities at their site.

f. For record keeping, Bausch Health has requested a copy of all received Annex No. 2 (Wholesaler/ Retailer Acknowledgment/ Reply Form) from the Authorized Distributor which will be sent to the email address: **customerservicedwc@bauschhealth.com**.
g. Bausch + Lomb has given the Authorized Distributor the approval to destroy all quarantined quantities from the impacted lot locally in accordance to the applicable laws and regulations.
h. A Destruction Certificate shall be provided from Authorized Distributor which conducted the destruction and shall include the product name, lot number (s), quantities. The destruction certificate shall be signed and stamped.

2. The Implementation of the Field Safety Corrective Action plan including retrieving of the affected quantities and destruction process is **August 30th,2021**. Further, it has been requested from the Authorized Distributor to communicate in advance to Bausch+Lomb any unforeseen challenges to meet the deadline.

Stage 2 (Consumer Level)

Bausch + Lomb has delegated this step to an external professional service provider (Sedgwick) which will manage this process on our behalf.

Consumers who may have these affected products in their possession should take the following steps:

1. Visit BLRecall.expertinquiry.com to verify the product is impacted.
2. If the product is impacted, stop using the product.
3. Register for further instructions at BLRecall.expertinquiry.com.
4. After following all instructions, discard the impacted product.

For more information on the recall or for assistance with registration, consumers should contact Sedgwick, the firm conducting this product recall on behalf of Bausch + Lomb, via email: BLRecall@Sedgwick.com, Toll-Free Number: **800-814-0020** between the hours of 11am to 8pm local time, Sunday – Saturday, or online at BLRecall.expertinquiry.com.

List of Attachments/ Annexes:

Attachment Number	Description
1	Media Recall Announcement (News Release)
2	Social Media Recall Posts
3	Recall Physical Posts (Notice)
4	Website Notice

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Annex Number	Description
1	Distributor Acknowledgment/ Reply Form
2	Wholesaler/ Retailer Acknowledgment/ Reply Form
3	Distributor, Wholesaler and Retailer Letters

For further information or questions regarding this recall, you may reach the below contacts based on the nature of the inquiry:

Topic	Contact Person	Contact Information
Product Recall Process Product Quality Complaint	Mazen Boughanem Quality Director, MENA	Mazen.boughanem@bauschhealth.com Phone No.: 00971 52 492 1474
Product Adverse Events	Rania El Asmar Head GDCM TMEA, Russia, CIS	Rania.ElAsmar@bauschhealth.com Phone No.: 00971 56 499 5638
Regulatory Affairs	Reham Habashi Regional Head of Regulatory Affairs - Medical Devices, MEA	Reham.Habashi@bauschhealth.com Phone No.: 00971 55 204 8440

We do thank you for your continued support and understanding as we maneuver through this process.

Sincerely,

JENNIFER R. HATCH
Notary Public - State of New York
No. 01HA6111879
Qualified in Wyoming County
My Commission Expires June 28, 2024

Name: Timo Jackle
Title: Vice President, Quality, Global Medical Devices,
Company: Bausch + Lomb Incorporated.

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Table A: Voluntary Recalled Product Information for KSA

Product Description	SKU	Lot Number	Original Distributed Quantity (each)
ReNu® MultiPlus Multi-Purpose Solution, 360 ml	81084718	MF1656	1,632
		MF1949	1,920
STARTER KIT Biotrue® Multi-purpose Solution, 60 ml	51085015	MF1831	624
STARTER KIT ReNu® MultiPlus Multi-Purpose Solution, 60 ml	84084715	MF1849	7,200
Total			**11,376**

Product Details	
Expiration Dates	May 2021 – February 2024
	

See below an example of the bottle and carton labels, which contain the lot number and expiration to easily identify the product. The lot number consists of two letters and four number (AA####) and the expiration is the four-digit year, hyphen, two digit month (YYYY-MM).

Label Examples

Lot and Expiration on Bottle Label	Lot and Expiration on Carton Label
AA#### YYYY-MM	AA#### YYYY-MM