URGENT RECALL

Regener-Eyes has issued a recall of two of its products. One of these products, Regener-Eyes LITE, has been sold in our office.

If you purchased this product for dry eyes, please check your supplies. The affected lot numbers are included in this notification.

The following letter outlines the recall notification:

Regenerative Processing Plant, LLC 34176 US Highway 19 N. Palm Harbor, FL 34684 Email: recall@regenerativeplant.org

Regenerative Processing Plant, LLC is issuing this urgent communication to inform you of a recall involving the following products:

Regener-Eyes Professional® (NDC: 82305-003-01)

Regener-Eyes Lite® (NDC: 82305-006-01)

Official recall form

This voluntary recall has been initiated due to a packaging integrity issue with the eyedropper dispensing applicators. Specifically: The absence of a backflow prevention mechanism. This poses a risk for potential illness and sickness. Backflow prevention mechanisms are critical to maintaining product sterility and ensuring user safety.

All Regener-Eyes bottles are sold through Eye Care Professionals and the Required Actions are:

- 1. Examine Your Inventory
- Immediately identify and quarantine all affected products. See Table 1 and II on the <u>Official</u> recall form page for lot numbers.
- 2. Notify Your Customers
- If you have distributed these products further, promptly notify your customers. Include a copy of this recall notification letter.

3. Destroy Affected Products

- Destroy them in accordance with local regulations.
- Complete <u>Official recall form</u>

Please complete our <u>Official recall form</u> to confirm receipt of this notification and describe the actions taken.

For Questions: Contact our Recall Coordinator at recall@regenerativeplant.org.

For Adverse Reactions or Quality Concerns: Report issues to the FDA MedWatch Adverse Event Reporting Program

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (Agency).

We value your cooperation and prompt attention to this matter as we work to ensure the safety of all users.

The affected lot numbers are as follows:

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P122022A	12/20/24
Regener-Eyes LITE	P122122A	12/21/24
Regener-Eyes LITE	P122122B	12/21/24
Regener-Eyes LITE	P122622A	12/26/24
Regener-Eyes LITE	P122622B	12/26/24
Regener-Eyes LITE	P122722A	12/27/24
Regener-Eyes LITE	P122722B	12/27/24
Regener-Eyes LITE	P122822A	12/28/24

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P122822B	12/28/24
Regener-Eyes LITE	P010223A	1/2/25
Regener-Eyes LITE	P010323LV1	1/3/25
Regener-Eyes LITE	P010523A	1/5/25
Regener-Eyes LITE	P010523B	1/5/25
Regener-Eyes LITE	P010923A	1/9/25
Regener-Eyes LITE	P011023LV2	1/10/25
Regener-Eyes LITE	P011223A	1/12/25
Regener-Eyes LITE	P011223B	1/12/25
Regener-Eyes LITE	P011623A	1/16/25
Regener-Eyes LITE	P011723LV3	1/17/25
Regener-Eyes LITE	P011923A	1/19/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P011923B	1/19/25
Regener-Eyes LITE	P012323A	1/23/25
Regener-Eyes LITE	P012323B	1/23/25
Regener-Eyes LITE	P012523A	1/25/25
Regener-Eyes LITE	P013123A	1/31/25
Regener-Eyes LITE	P020223A	2/2/25
Regener-Eyes LITE	P020623A	2/6/25
Regener-Eyes LITE	P020823A	2/8/25
Regener-Eyes LITE	P020923A	2/9/25
Regener-Eyes LITE	P021323A	2/13/25
Regener-Eyes LITE	P021523A	2/15/25
Regener-Eyes LITE	P021523B	2/15/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P021623A	2/16/25
Regener-Eyes LITE	P022023A	2/20/25
Regener-Eyes LITE	P022123A	2/21/25
Regener-Eyes LITE	P022323A	2/23/25
Regener-Eyes LITE	P022723A	2/27/25
Regener-Eyes LITE	P030123A	3/1/25
Regener-Eyes LITE	P030223A	3/2/25
Regener-Eyes LITE	P030623A	3/6/25
Regener-Eyes LITE	P030723A	3/7/25
Regener-Eyes LITE	P030823A	3/8/25
Regener-Eyes LITE	P030923A	3/9/25
Regener-Eyes LITE	P031323A	3/13/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P031423A	3/14/25
Regener-Eyes LITE	P031523A	3/15/25
Regener-Eyes LITE	P031623A	3/16/25
Regener-Eyes LITE	P032023A	3/20/25
Regener-Eyes LITE	P032123A	3/21/25
Regener-Eyes LITE	P032223A	3/22/25
Regener-Eyes LITE	P032723A	3/27/25
Regener-Eyes LITE	P032823A	3/28/25
Regener-Eyes LITE	P032923A	3/29/25
Regener-Eyes LITE	P033023A	3/30/25
Regener-Eyes LITE	P040323A	4/3/25
Regener-Eyes LITE	P040423A	4/4/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P040523A	4/5/25
Regener-Eyes LITE	P040623A	4/6/25
Regener-Eyes LITE	P041023A	4/10/25
Regener-Eyes LITE	P041123A	4/11/25
Regener-Eyes LITE	P041223A	4/12/25
Regener-Eyes LITE	P041323A	4/13/25
Regener-Eyes LITE	P041723A	4/17/25
Regener-Eyes LITE	P041823A	4/18/25
Regener-Eyes LITE	P041923A	4/19/25
Regener-Eyes LITE	P042023A	4/20/25
Regener-Eyes LITE	P042423A	4/24/25
Regener-Eyes LITE	P042523A	4/25/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P042623A	4/26/25
Regener-Eyes LITE	P050123A	5/1/25
Regener-Eyes LITE	P050223A	5/2/25
Regener-Eyes LITE	P050323A	5/3/25
Regener-Eyes LITE	P050823A	5/8/25
Regener-Eyes LITE	P050923A	5/9/25
Regener-Eyes LITE	P051023A	5/10/25
Regener-Eyes LITE	P051123A	5/11/25
Regener-Eyes LITE	P051523A	5/15/25
Regener-Eyes LITE	P051623A	5/16/25
Regener-Eyes LITE	P051723A	5/17/25
Regener-Eyes LITE	P052223A	5/22/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P052323A	5/23/25
Regener-Eyes LITE	P052423A	5/24/25
Regener-Eyes LITE	P052523A	5/25/25
Regener-Eyes LITE	P053023A	5/30/25
Regener-Eyes LITE	P053123A	5/31/25
Regener-Eyes LITE	P060123A	6/1/25
Regener-Eyes LITE	P060223A	6/2/25
Regener-Eyes LITE	P060523A	6/5/25
Regener-Eyes LITE	P060623A	6/6/25
Regener-Eyes LITE	P060723A	6/7/25
Regener-Eyes LITE	P060823A	6/8/25
Regener-Eyes LITE	P061223A	6/12/25

Product Name	Lot Number	Exp Date
Regener-Eyes LITE	P061323A	6/13/25
Regener-Eyes LITE	P061423A	6/14/25