PRODUCT MARKET WITHDRAWAL - Expanded Similasan Eye Drops 102423

Date of Issue – 2023-10-24 **Recall #** 101086

UNFI was notified by the manufacturer of a food safety event. Records indicate your location may have received impacted product. Refer to this notice and the supplier letter to identify and remove impacted product from the marketplace. Enter your findings into Recall Infolink.

Impacted UNFI Business Units: Natural & Conventional
Event Classification: Market Withdrawal

Supplier Name: EMERSON HEALTHCARE L
Supplier Contact: Jennifer Cameron, cameron@similasanusa.com, 303.539.4060 x108
Product Issue: Voluntary withdraw from Similasan as a result of the FDA warning letter sent out on 9/11/2023. Several concerns that the FDA had about the marketing and manufacturing of homeopathic eye drops and the safety of one of the preservatives used in their manufacture, silver sulfate.
Retail Disposition : Destruction

Brand Name & Description	Pack Size	Case UPC	Unit UPC	Impacted Best by Date(s)/ Lot Codes (MUST provide Best By Date)
Similasan – Aging Eye Relief 10ml	6	60094841300469	094841300467	All Best By Dates

Cease distribution on the above product. Isolate the product in a secure location
Follow the below instructions to ensure proper disposition of the product.

1. Remove items listed above from sales floor, displays and back stock.
2. Count the units of impacted product (**only date(s)/lot code(s) listed above**) and record in Recall Infolink.
3. Impacted product must not re-enter commerce or be made available for consumption by any means.
4. **For Credit:** Enter your impacted product count (**only date(s)/lot code(s) listed above**) through Recall Infolink
5. Complete disposition ASAP
6. Inspect inbound product for the next 48 hours to ensure no impacted product is received

September 28, 2023

To Our Valued Partners,

As you know, eight ophthalmic companies, including Similasan, recently received warning letters from the FDA which brought up several concerns that the FDA had about the marketing and manufacturing of homeopathic eye drops and the safety of one of the preservatives used in their manufacture, silver sulfate.

Each company has 15 business days to reply to the FDA to indicate how they intend to respond to their respective letters. Similasan's US leadership team has been in discussions with our retail partners, our manufacturing centers, and our shareholders as we develop an appropriate response.

Pending resolution of the FDA concerns, we have voluntarily suspended the sale and distribution of all Similasan eye drop products to US retailers. We are cooperating with the FDA to quickly resolve this matter.

Our ear drops and other ear relief products are not affected by the FDA's action, and we want to thank you for your continued support of them and of the Similasan brand as we work towards a solution with the FDA. We will continue to update you as we have more clarity.

Sincerely,

Dan Quail

President, North America

Similasan USA

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