





To: AmeriHealth Caritas Next and First Choice Next Providers

Date: July 25, 2025

Subject: Nostrum Laboratories, Inc. Issues Voluntary Nationwide Recall of Sucralfate Tablets USP 1 Gram Within Expiry

On July 14th the FDA released a notification announced on July 11, 2025 by <u>Nostrum Laboratories</u> of a voluntary nationwide recall of Sucralfate Tablets USP 1 Gram. [<u>EINPresswire.comExternal Link Disclaimer</u>] -- Nostrum Laboratories, Inc. ("Nostrum Labs") filed Chapter 11 bankruptcy on September 30, 2024. In connection with that filing, the company has ceased and shutdown operations and terminated its operational employees at all domestic U.S. sites. Nostrum Labs is initiating a voluntary recall of Sucralfate Tablets USP 1 gram, all lots within expiry, as a result of the closures and discontinuation of its Quality activities.

This recall pertains only to Sucralfate Tablets USP 1 gram, all lots with expiry, manufactured by Nostrum Labs after June 2023. No other Nostrum Labs products are affected by this recall. Nostrum Labs distributed the product at issue here to wholesalers, retailers, manufacturers, medical facilities, and repackagers.

It cannot be guaranteed that any lots of this product that are still within expiry will meet all intended specifications through the labeled shelf life of the product. Further distribution or use of any remaining product on the market should cease immediately.

Nostrum Labs is notifying its distributors and direct consignees for this product by email and U.S. mail and is requesting they immediately further notify their subsidiaries, individual receiving sites or warehouses, customers, retailers, and consumers. All lots of this product should be destroyed; Nostrum Labs is not accepting any returns of this product.

Risk Statement: The discontinuation of Nostrum Labs' quality program means that the Company is unable to assure that this product meets the identity, strength, quality, and purity characteristics that it is purported or represented to possess. While specific risks to patients from use of an adulterated product cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such a product. Nostrum Labs has not received any reports of adverse events related to this recall.

Customers with questions regarding this recall can contact Nostrum Labs at recall.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

AmeriHealth Next and First Choice Next are individual and family health plans offered by certain companies within the AmeriHealth Caritas Family of Companies. AmeriHealth Caritas Next is offered by AmeriHealth Caritas VIP Next, Inc. in Delaware; AmeriHealth Caritas Florida, Inc. in Florida; AmeriHealth Caritas North Carolina, Inc. in North Carolina; and First Choice Next by Select Health of South Carolina, Inc. in South Carolina.



- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form or submit by fax to 1-800-FDA-0178.

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

AmeriHealth Caritas Next and First Choice Next is sending notifications to all members and their prescribers who have filled a prescription within the past six (6) months for Sucralfate Tablets USP 1 gram manufactured by Nostrum Labs of this voluntary recall.

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