

Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-020-CG August 29, 2025

FDA announced that 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. Nostrum Labs has not received any reports of adverse events related to this recall. 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.

RECOMMENDATIONS

- 1. 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.
- 2. All lots of this product should be destroyed; Nostrum Labs is not accepting any returns of this product.
- 3. Customers with questions regarding this recall can contact Nostrum Labs at recall.com.
- 4. 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.
- 5. Review your inventory to identify existence of recalled products.
- 6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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

SUMMARY:

Company Announcement Date: July 11, 2025 FDA Publish Date: July 14, 2025

Product Type: Drugs

Reason for Announcement:Company closure and discontinuation of quality

activities.

Company Name:Nostrum Laboratories, Inc.
Nostrum Laboratories

Product Description:Sucralfate Tablets USP 1 gram

Company Announcement

NEW YORK, DC, UNITED STATES, July 11, 2025 /<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.

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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 <u>recallcoordinator@nostrumlabsrecall.com</u>. 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.

- 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 pre-addressed form or submit by fax to 1-800-FDA-0178

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