

FDA Drug Recall**NOSTRUM LABORATORIES, INC. ISSUES VOLUNTARY NATIONWIDE RECALL OF
SUCRALFATE TABLETS USP 1 GRAM WITHIN EXPIRY****7/14/2025**

Nostrum Laboratories, Inc., is voluntarily recalling all lots of Sucralfate Tablets USP 1 gram 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.

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.

Sucralfate Tablets USP 1 gram is an oral tablet used to treat ulcers.

The recalled NDCs are included in the table below:

Product	Lot Number	NDC	Manufactured Dates
Sucralfate Tablets USP 1 gram	All Lots	29033-0003-05	06/1/2023-07/17/2025
		29033-0003-01	

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.

Questions regarding this recall can be directed to Nostrum Labs at recallcoordinator@nostrumlabsrecall.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.

- 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.

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

Source: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-sucralfate-tablets-usp-1-gram-within>