



Clifton Health Department Food Recall Notification



Food/Drug/Pet Recall: Precision Dose, Inc.

Precision Dose, Inc. is voluntarily recalling all lots of Chlorhexidine Gluconate Oral Rinse USP, 0.12%, 15mL Unit Dose Cups bearing an expiration date from 1/31/2021 - 02/28/2022 (see specific lots below) to the consumer level. Precision Dose, Inc. was notified by the manufacturer of the product, Sunstar Americas, Inc., that this product may be contaminated with the bacteria *Burkholderia lata*.

From information provided by the manufacturer, Sunstar Americas, Inc., use of the defective product in the immunocompetent host may result in oral and, potentially, systemic infections requiring antibacterial therapy. In the most at-risk populations, the use of the defective product may result in life-threatening infections, such as pneumonia and bacteremia. To date, no adverse events have been reported to Precision Dose, Inc. related to this recall.

The prescription oral rinse product, available through healthcare professionals only, is indicated for use as part of a professional program for the treatment of gingivitis and the product impacted is:

- . Distributed in cases each containing 3 shrink-wrapped plastic trays each with 10 unit dose cups, 30-pack. NDC 68094-028-62
- . Distributed in cases each containing 10 shrink-wrapped plastic trays each with 10 unit dose cups, 100-pack. NDC 68094-028-61

Chlorhexidine Gluconate Oral Rinse was distributed nationwide in the USA to pharmaceutical wholesalers.

Precision Dose, Inc. is notifying its consignees directly and is arranging for return of all recalled product. Patients, pharmacies, and healthcare facilities in possession of these products should stop using and dispensing immediately.

Consumers with questions regarding this recall can contact Precision Dose, Inc. at 1 (800) 397-9228 (Monday-Friday, 8:00 AM to 4:30 PM Central Time) or by email to customercare@precisiondose.com. Consumers should contact their physician or healthcare provider if they have experienced problems that may be related to using this drug product.

Affected products and lot numbers follow below:

AFFECTED LOTS	Chlorhexidine Gluconate Oral Rinse USP, 0.12%	LOT NUMBER	EXPIRATION DATE	NDC NUMBER
502037		01/31/2021	68094-028-61	
68094-028-62				
502040		01/31/2021	68094-028-61	



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68094-028-62
502043 01/31/2021 68094-028-61
68094-028-62
502494 08/31/2021 68094-028-61
68094-028-62
502757 08/31/2021 68094-028-61
502677 09/30/2021 68094-028-61
502693 10/31/2021 68094-028-61
502728 10/31/2021 68094-028-61
502759 10/31/2021 68094-028-62
502771 11/30/2021 68094-028-61
68094-028-62
502784 11/30/2021 68094-028-61
502824 12/31/2021 68094-028-61
502925 02/28/2022 68094-028-61

Patients should contact their physician or healthcare provider if they have additional questions or concerns. 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
- . Regular Mail or Fax: Download form 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.

Consumers may contact the firm at:

Email: customercare@precisiondose.com

www.precisiondose.com

Company Contact:

Mark Franzen

1 (800) 397-9228 x226

mfranzen@precisiondose.com