## Sunstar Americas – Recall of Paroex® (chlorhexidine gluconate)

- On December 28, 2020, the FDA announced a voluntary, consumer level recall of all lots of Sunstar America's Paroex (chlorhexidine gluconate) 12% oral rinse, labeled with expiration dates of 12/31/20 – 9/30/22, due to contamination with *Burkholderia lata*. This is an expansion of the recall initially announced on October 27, 2020.

| Product Description | NDC# | Lot# (Expiration Date) |
|---|---|---|
| Paroex (chlorhexidine gluconate) oral rinse, 0.12%, 16 fl. oz. amber bottle | 52376-021-02 | All lots with expiration date from 12/31/2020 - 9/30/2022 |
| Paroex (chlorhexidine gluconate) oral rinse, 0.12%, 4 fl. oz. amber bottle | 52376-021-04 | |

- Paroex is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing.
- 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.
- Use of the contaminated product on patients with pre-existing respiratory conditions, including those infected with Covid-19, is particularly unsafe. To date, Sunstar has received 29 adverse event reports related to this recall.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled Paroex.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Sunstar by phone at **1-800-528-8537** or by email at **us.pcr@us.sunstar.com** for further information regarding this recall.