Taro – Recall of clobetasol ointment

- On December 30, 2021, the FDA announced a consumer level recall of one lot of Taro's clobetasol propionate 0.05% ointment due to the presence of *Ralstonia pickettii* (*R. pickettii*) bacteria, which was discovered by the manufacturer through routine testing.

- The recalled lot was distributed between November 16 and December 6, 2021.

Product Description	NDC	Lot # (Expiration Date)
Clobetasol propionate ointment 0.05%, 60 g tube	51672-1259-3	AC13786 (12/2022)

- Clobetasol propionate ointment are super-high potency corticosteroid formulations indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

- *R. pickettii* is present in the natural environment and for healthy individuals with intact skin, is unlikely to cause any localized or systemic infections. However, for individuals who are immunocompromised, or whose skin is not intact, there is a reasonable possibility that systemic infections may occur if the product is contaminated with *R. pickettii* due to the presence of the corticosteroid component which enhances absorption of the ointment.

- If this bacterium is circulating in the human blood stream it can cause life-threatening, invasive infections such sepsis, pneumonia, meningitis, inflammation of the bone or bone marrow, and infection in the joint fluid and joint tissues.

- To date, Taro has not received any adverse event reports related to the recalled lot.

- Patients should contact their health care provider if they have experienced any problems that may be related to using the recalled clobetasol propionate ointment.

- Anyone with the recalled product on hand should stop use and distribution and return product to the place of purchase.

- Contact Taro by phone at **1-866-923-4914** or by email at **TaroPVUS@taro.com** for more information about the recall.