



**Taro Pharmaceutical Industries Ltd.
c/o Taro Pharmaceuticals U.S.A., Inc.**

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(NYSE: TARO)

**TARO PHARMACEUTICALS U.S.A. ISSUES VOLUNTARY NATIONWIDE RECALL OF
CLOBETASOL PROPIONATE OINTMENT USP, 0.05%, 60 g TUBES, LOT AC13786
DUE TO MICROBIAL CONTAMINATION**

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FOR IMMEDIATE RELEASE - **Hawthorne, NY, December 27, 2021** – Taro Pharmaceuticals U.S.A., Inc. (“Taro” or the “Company”) is voluntarily recalling one (1) lot of Clobetasol Propionate Ointment USP, 0.05% packaged in 60 g tubes, to the consumer level. This recall ONLY applies to tubes labeled with “Lot AC13786” and “Exp Dec 2022”. No other lots of this product are impacted. Lot AC13786 is being recalled due to the presence of *Ralstonia pickettii* bacteria (“*R. pickettii*”), which was discovered by the manufacturer through routine testing.

R. pickettii is present in the natural environment (soil, water) 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 (i.e. sunburn, psoriasis, abrasions), 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 this lot.

The one (1) lot being recalled is as follows:

| Lot # | Amount | Expiration Date |
|--------------|---------------|------------------------|
| AC13786 | 96 units | December 2022 |

Clobetasol Propionate Ointment USP, 0.05% is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses and is packaged in 60 g aluminum tubes with polypropylene puncture-tip caps. Each 60 g tube is labeled to indicate the name of the product, Clobetasol Propionate Ointment USP, 0.05% and the NDC # 51672-1259-3 (see image of container label below). The Lot Number and Expiration Date are displayed on the bottom of each tube and the end flap of the product carton.

Ninety-six (96) units of Lot AC13786 were distributed to two wholesale distributors in the U.S. market between **November 16 and December 6, 2021**. These two wholesale distributors may have further distributed this lot to their retail customers for prescription dispensing to patients who were prescribed Clobetasol Propionate Ointment USP, 0.05%, 60 g.



Taro has notified the affected distributors by phone, e-mail, and letters via U.S. Mail and is arranging for return of any containers of Clobetasol Propionate Ointment USP, 0.05%, 60 g, Lot AC13786 (expiration date of December 2022). Retail customers that have any quantities of Lot AC13786 which is being recalled, should stop distribution and return any unsold units to their wholesaler.

Consumers with questions regarding this recall can contact Taro by calling 1-866-923-4914 or by e-mail at TaroPVUS@taro.com, Monday through Friday between 7:00 am and 7:00 pm, U.S. Central Time. 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 US Food and Drug Administration.

SAFE HARBOR STATEMENT

Certain statements in this announcement are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements that do not describe historical facts or that refer or relate to events or circumstances the Company “estimates,” “believes,” or “expects” to happen or similar language, and statements with respect to the voluntary recall of Clobetasol Propionate Ointment USP, 0.05%, 60 g. Although the Company believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurances that its expectations will be attained. Further updates, if appropriate, will be detailed from time to time in the Company’s SEC reports, including its Annual Reports on Form 20-F. Forward-looking statements are applicable only as of the date on which they are made.
