



**TARO** Pharmaceutical Industries Ltd

## **Taro USA Receives Tentative Approval for Mometasone Furoate Topical Solution USP, 0.1% -Lotion-ANDA**

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HAWTHORNE, N.Y.--(BUSINESS WIRE)--Dec. 6, 2004--Taro Pharmaceutical Industries Ltd. (Nasdaq: TARO) reported today that Taro Pharmaceuticals U.S.A., Inc. ("Taro USA"), its U.S. affiliate, has received tentative approval from the U.S. Food and Drug Administration ("FDA") for its Abbreviated New Drug Application ("ANDA") for Mometasone Furoate Topical Solution USP, 0.1% (Lotion) ("mometasone lotion").

Taro's mometasone lotion is a prescription topical corticosteroid product used primarily for the relief of inflammatory skin conditions. The Taro product is intended to be marketed as a generic version of Schering-Plough's Elocon(R) lotion. According to industry sources, U.S. sales of Elocon(R) lotion were approximately \$10 million in 2003.

The tentative approval for mometasone lotion is an FDA determination that Taro USA's ANDA submission for this product currently satisfies the substantive requirements for approval, subject to the expiration of all relevant patents or statutorily imposed exclusivities, restrictions and any new information that may come to the FDA's attention. Tentative approvals do not grant marketing rights; a company may only market a product upon receiving final approval for an ANDA submission.

Recently, Taro USA also received final approval of its ANDA for Mometasone Furoate Ointment, USP 0.1% and tentative approval of its ANDA for Mometasone Furoate Cream, USP 0.1%.

Taro Pharmaceutical Industries Ltd. is a multinational, science-based pharmaceutical company, dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality healthcare products.

For further information on Taro Pharmaceutical Industries Ltd., please visit the Company's website at [www.taro.com](http://www.taro.com).

Certain statements in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company's mometasone furoate products. Although Taro Pharmaceutical Industries Ltd. believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurance that its expectations will be attained. Factors that could cause actual results to differ include industry and market conditions; slower than anticipated penetration of new markets; physician, pharmacist or patient acceptance of Taro's mometasone furoate products; receipt of final approval from the FDA for the ANDA for mometasone cream or lotion; changes in the Company's financial position; regulatory actions; and, other risks detailed from time to time in the Company's SEC reports, including its 2003 Annual Report on Form 20-F. Forward-looking statements speak only as of the date on which they are made. The Company undertakes no obligation to update, change or revise any forward-looking statements, whether as a result of new information, additional or subsequent developments or otherwise.

CONTACT: Taro Pharmaceutical Industries Ltd.  
Daniel Saks, 914-345-9000 ext. 6208  
or  
Kevin Connelly, 914-345-9000 ext. 6338

SOURCE: Taro Pharmaceutical Industries Ltd.