TARO PHARMACEUTICAL INDUSTRIES LTD Form 6-K February 10, 2009 **UNITED STATES SECURITIES AND EXCHANGE COMMISSION** Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of February, 2009

Commission File Number 000-22286

Taro Pharmaceutical Industries Ltd.

(Translation of registrant's name into English)

14 Hakitor Street, Haifa Bay 26110, Israel

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-____.

Taro Receives FDA Warning Letter Following Inspection of Its Canadian Manufacturing Facility

The Company Has Already Taken Corrective Action Regarding Many of the Comments Contained in the Letter

HAWTHORNE, N.Y.--(BUSINESS WIRE)--February 6, 2009--Taro Pharmaceutical Industries Ltd. ("Taro," the "Company," Pink Sheets: TAROF) announced that yesterday, February 5, 2009, it received a warning letter from the U.S. Food and Drug Administration ("FDA") regarding the inspection of the Company's Canadian manufacturing facility in July 2008. This is the first such letter that the Company or any of its affiliates has ever received.

The observations set forth in the letter include concerns about certain of the Company's quality control systems, including failure to complete investigations of quality issues in a timely manner.

The Company is committed to working with the FDA to resolve all issues expeditiously. The Company further said that it plans to respond to the letter within 30 days, as required. In addition, the Company said it has already corrected many of the observations cited during the July 2008 inspection. Corrective actions began immediately following the inspection last year and are still underway, including the retention of quality control consultants.

The Company noted that the observations cited in the letter do not relate to any of the Company's other facilities. It is also noted that until remedial action is complete and the FDA has confirmed compliance with current Good Manufacturing Practices ("cGMPs"), new applications listing the Canadian facility as a manufacturing location of finished dosage forms may not be approved.

About Taro

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.

SAFE HARBOR STATEMENT

Certain statements in this release 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 and statements that refer or relate to events or circumstances the Company "estimates," "believes," or "expects" to happen, "should" happen, or similar language, and statements with respect to the remediation of FDA observations and FDA confirmation of Company compliance with cGMPs, as described in this press release. Although Taro Pharmaceutical Industries Ltd. 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. Factors that could cause actual results to differ include regulatory actions taken by the FDA, general domestic and international economic conditions, industry and market conditions, changes in the Company's financial position, litigation brought by any party in any court in Israel, the United States, or any country in which Taro operates, litigation, regulatory actions and legislative actions in the countries in which Taro operates, and other risks detailed from time to time in the Company's SEC reports, including its Annual Reports on Form 20-F. Forward-looking statements speak only as of the date on which they are made. The Company undertakes no obligations to update, change or revise any forward-looking statement, whether as a result of new information, additional or subsequent developments or otherwise.

CONTACT:

Kekst and Company Roanne Kulakoff, 212-521-4827

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 10, 2009

TARO PHARMACEUTICAL INDUSTRIES LTD.

By: <u>/s/ Tal Levitt</u> Name: Tal Levitt Title: Director and Secretary