March 8, 2016

IMPORTANT TO VERIFY PRODUCT IDENTITY PRIOR TO DISPENSING

Subject:	**Tretinoin Capsules, 10 mg, Potential Product Mix-Up** **Lot # 49816M13**

Dear Healthcare Provider:

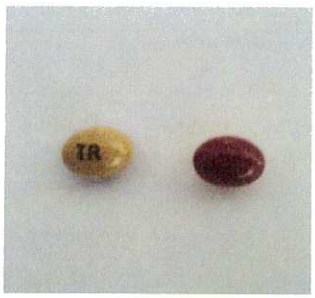
The purpose of this letter is to alert you that you must verify the contents of all supplied bottles of Par Pharmaceutical ("Par") Tretinoin Capsules prior to dispensing because of an issue that occurred at a manufacturing facility.

A recent problem with Par's supplier in France resulted in the potential of certain drug products improperly being placed in containers containing other drug products. While no mix-ups have yet been identified with Tretinoin Capsules at this time, Par is bringing this situation to your attention to have you verify the identity of each individual capsule prior to dispensing to patients. Because of the critical necessity of this drug, Par is asking Healthcare Providers to take this necessary step to ensure that patients receive the correct product.

Please open each bottle of Tretinoin Capsules, 10 mg, supplied by Par and carefully verify, prior to dispensing to patients, each capsule in the bottle is a Tretinoin Capsule, 10 mg. If you discover any capsules that do not conform fully to the description and picture provided below, they must not be dispensed to the patient. Please immediately call both our Medical Information departments and the U.S. Food and Drug Administration to report the finding. Contact information appears the end of this letter.

Par's Tretinoin Capsules are supplied as 10 mg capsules, two-tone (lengthwise) with reddish-brown opaque on one side and yellow on the other side of a gelatin shell. The yellow side of the capsule is imprinted with "TR" in black.

Pictures of both sides of the capsules are also provided for reference below. For additional information about Par's Tretinoin Capsules, please refer to the "How Supplied" section of the attached Prescribing Information.



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Healthcare Providers and patients should report adverse events and medication errors to Par's Medical Information department at 800-828-9393. Adverse events or quality problems experienced with the use of this product should also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, 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.

Sincerely,

Anh Tran-Cao
Senior Director, Regulatory Affairs
Par Pharmaceutical

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