TEVA U.S. Generics

May 10, 2016

Drug Shortage Staff
Food and Drug Administration
WO 22, Room 6204
10903 New Hampshire Avenue
Silver Spring, MD 20993

FDA DRUG SHORTAGE RESPONSE

ANDA # 077684
TRETINOIN CAPSULES, 10mg

Dear FDA Drug Shortage:

Teva Pharmaceuticals USA, Inc. is hereby providing this letter in response to the Food and Drug Administration (FDA) letter dated April 19, 2016 sent under Section 506C (f) of the Federal Food, Drug, and Cosmetic Act concerning the failure to notify FDA of interruption in manufacturing of Tretinoin Capsules, 10 mg (ANDA 077684) .

Teva would like to provide the Agency with a chronology of events concerning the reason for the interruption in manufacturing of this product along with the communication shared with the Agency.

In November 2015, Teva had low inventory of Tretinoin Capsules as new production was being planned. The active pharmaceutical ingredient (API) manufacturer had supplied material that did not conform to Teva's specification. This issue resulted in delays in our scheduled production which in turn, caused a backorder for the product. Throughout the process Teva worked closely with the API manufacturer who committed to delivering a new lot of API to Teva by February 2016 that would meet Teva's specification.

(b) (4) Teva does not hold a majority of the market share for Tretinoin Capsules (we hold approximately % market share). When considering our market share and the API manufacturer's communicated delivery commitment date, Teva did not realize that our temporary backorder situation would have created a drug shortage. It is our understanding that this drug shortage was also attributed and further exasperated by other approved manufacturers who also were experiencing difficulty in manufacturing and supplying the commercial market.

On February 16, 2016, FDA contacted Teva to inquire about supply. Teva informed the Agency that conforming API had been received and manufacture would start in February. Teva tested the API, manufactured, packaged, tested the final dosage form and dispositioned the Tretinoin Capsules to the market by March 11, 2016.

During the month of February while production was in progress, Teva's Compassionate Use Team set up a system for emergency supplies of Tretinoin Capsules. Fifteen bottles of reserve samples were made available for emergency use. By March 21, 2016, Teva was off of backorder.

Teva is committed to the needs of our patients and we are committed to working diligently to assure quality products are supplied. Understanding the significance of supplying the commercial market with this product, Teva was able to manufacture, package, test and release product in approximately 1 month which is indicative of our commitment to our patients.

We hope this written response appropriately satisfies the Agency's request of noncompliance for the interruption in manufacturing that led to an unforeseeable disruption in the supply of Tretinoin capsules in February 2016.

This letter may contain trade secrets and confidential commercial information (collectively, the "Protected Information"). We request that the Protected Information not be disclosed outside of the Government pursuant to FOIA Exemption 4 (5 U.S.C. section 552(b)(4)) and 18 U.S.C. section 1905.

Sincerely,

Joseph M. DeVito, Pharm.D.
Vice President, Quality
Teva Pharmaceuticals