



JAN 19 A9:35

January 17, 2006

Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

**Re: Docket Number 2005P-0417/CP1
Suitability Petition (Labeling)**

Dear Sir or Madam:

Reference is made to the October 18, 2005 Suitability Petition # 2005P-0417/CP1 requesting that FDA declare that tretinoin cream in strengths of 0.0375% and 0.075% are suitable for submission in ANDAs. Reference is also made to the January 13, 2006 telephone conversation between Dr. Cecelia Parise and Triax Pharmaceuticals in which Dr. Parise requested proposed labeling for the new tretinoin strengths and a copy of the approved label for the reference listed drug, Retin-A[®]

In accordance with 21 CFR§ 314.93 (d), Triax Pharmaceuticals hereby submits proposed labeling for Tretinoin Cream, USP that includes the two additional strengths that are the subject of the aforementioned suitability petition.

Pursuant to 21 CFR§ 10.20(a), this submission contains four copies.

The undersigned certify, that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners that are unfavorable to the petition.

Sincerely,

Keith S. Rotenberg, Ph.D.
Senior Vice President, Regulatory Affairs and Operations

2005P-0417

SUP 1

Enclosures