



Triax Pharmaceuticals, LLC  
Attention: Keith S. Rotenberg, Ph.D.  
20 Commerce Drive, Suite 232  
Cranford, NJ 07016

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MAY 09 2007

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Food and Drug Administration  
Rockville MD 20857

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Docket No. 2005P-0417/CP1

Dear Dr. Rotenberg:

This is in response to your petition filed on October 18, 2005, and your supplements dated, January 17, 2006, and January 5, 2007, requesting permission to file Abbreviated New Drug Applications (ANDAs) for the following drug products: Tretinoin Cream, 0.0375% and 0.075%. The reference listed drug products to which you refer in your petition are Retin-A (Tretinoin) Cream, 0.025%, 0.05%, and 0.1%, approved under NDAs 19-049, 17-522, and 17-340 held by Johnson & Johnson.

Your request involves changes in strengths from that of the listed drug products. You are requesting permission to file ANDAs for two intermediate strengths (i.e., 0.0375% and 0.075%) of tretinoin cream which fall between the already approved strengths (i.e., 0.025%, 0.05% and 0.01%). The changes you request are the types of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved.<sup>1</sup> This letter represents the Food and Drug Administration's (FDA) determination that ANDAs may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The FDA finds that the changes in strengths for the specific proposed drug products do not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug products are the same as those of the listed drug products, and the labeling for the listed

<sup>1</sup> In addition, we acknowledge the comments submitted by Johnson & Johnson on February 14, 2006, and the comments submitted by David Lowe on March 17, 2006. With regard to Johnson & Johnson's statements respecting the need for data to support approval of a generic version of a topical drug, we note that products approved under an ANDA considered pursuant to a Section 505(j)(2)(C) suitability petition need not be found to be bioequivalent to the listed drug, but they must demonstrate that they have the same therapeutic effect as the listed drug (see 21 CFR 314.93(d)). The Agency has determined that sameness of therapeutic effect for these two interim strength Tretinoin Cream products can be demonstrated using comparative bioavailability data. See 21 USC 355(j)(8)(A)(ii); 21 CFR 320.24(b)(4), 320.24(b)(6). FDA will determine how Triax will demonstrate comparative bioavailability (whether through a relative bioavailability trial with a clinical end point or by some other method) as part of the ANDA review process, as it would for any ANDA submitted pursuant to a suitability petition. This question need not be resolved by the Agency at this time.

2005P-0417

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drugs supports the use of these interim strengths (the labeling indicates that the products should be applied once daily, regardless of the strength). The FDA concludes, therefore, that investigations to show safety and effectiveness are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

The approval of this petition to allow ANDAs to be submitted for the above-referenced drug products does not mean that the FDA has determined that ANDAs will be approved for the drug products. The determination of whether ANDAs will be approved is not made until the ANDAs are submitted and reviewed by the FDA.

To permit review of your ANDA submissions, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocols for these drug products to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDAs. During the review of your applications, the FDA may require the submission of additional information.

Please be advised that you are not permitted to make claims beyond those approved in the labeling of the reference listed drugs. Any claims beyond those in the approved labeling will be subject to enforcement action. Your statements in the petition regarding improved patient compliance, tolerance to treatment, minimizing side effects and improving tolerability, thereby increasing effectiveness of tretinoin topical therapy in a given patient, and skin irritation cannot be supported by data that would be reviewable in an ANDA. If you wish to make these types of claims, you should submit an NDA under section 505(b) that contains data to support these types of claims, not an ANDA.

The listed drug products to which you refer in your ANDAs must be the ones upon which you based this petition. In addition, you should refer in your ANDAs to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submissions. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research