



ANDA 078868

Apotex Inc.
U.S. Agent for: Apotex Corp.
Attention: Kiran Krishnan
Director, Regulatory Affairs
2400 North Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on August 10, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tizanidine Hydrochloride Capsules, 2 mg (base), 4 mg (base), and 6 mg (base).

Reference is also made to your amendments dated May 11, August 19, and September 7, 2011.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Tizanidine Hydrochloride Capsules, 2 mg (base), 4 mg (base), and 6 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zanaflex Capsules 2 mg (base), 4 mg (base) and 6 mg (base), respectively, of Acorda Therapeutics Inc. (Acorda). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Acorda's Zanaflex Capsules, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,455,557 (the '557 patent), is scheduled to expire on November 28, 2021.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '557 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tizanidine Hydrochloride Capsules, 2 mg (base), 4 mg (base), and 6 mg (base), under this ANDA. You have notified the agency that Apotex Corp. (Apotex) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '557 patent was initiated against Apotex within the statutory 45-day period in the United States District Court for the District of New Jersey [Acorda Therapeutics Inc. v. Apotex Inc. and Apotex Corp., Civil Action No. 07-cv-4937-GEB-MCA]. You have also notified the agency that the court decided that the '557 patent is invalid; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Apotex was the first ANDA applicant for Tizanidine Hydrochloride Capsules, 2 mg (base), 4 mg (base), and 6 mg (base), to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Apotex may be eligible for 180 days of generic drug exclusivity for Tizanidine Hydrochloride Capsules, 2 mg (base), 4 mg (base), and 6 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Apotex failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Apotex's eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Apotex begins commercial marketing of Tizanidine Hydrochloride Capsules, 2 mg (base), 4 mg (base), and 6 mg (base), or (b) at any time prior to the expiration of the last listed patent if Apotex has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required).

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KEITH O WEBBER
02/03/2012