March 23, 2004
ANDA 75-414

Martec Scientific, Inc.
Attention: Arthur Fiacco
1800 N. Topping Avenue
P.O. Box 33510
Kansas City, MO 64120-3510

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 12, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nifedipine Extended-release Tablets USP, 90 mg.

Reference is made to your amendments dated June 28, August 10, and August 11, 1999; January 28, March 15, June 3, July 3, July 11, and July 16, 2002; and February 27 (two amendments), August 27, September 10, and September 11, 2003. Reference is also made to your correspondence dated December 8, 1998; February 9, 1999; June 3, 2002; and September 24, 2003, addressing patent issues associated with this drug product.

The listed drug product (RLD) referenced in your application, Procardia® XL Extended-release Tablets, 90 mg, of Pfizer Laboratories, is subject to a period of patent protection. As noted in the Agency's publication Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 5,264,446 (the '446 patent) is scheduled to expire on November 23, 2010. Your application contains a paragraph IV certification to the '446 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that the '446 patent will not be infringed by your manufacture, use, or sale of Nifedipine Extended-release Tablets USP, 90 mg. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA may be made effective immediately, unless an action is brought against Martec Scientific, Inc. (Martec) for infringement of the '446 patent that was the subject of the paragraph IV certification. This action must be brought against Martec prior to the expiration of forty-five (45) days from the date the notice you provided under paragraph (2)(B)(i) was received by

the NDA/patent holder(s). You have notified the agency that Martec complied with the requirements of Section 505(j)(2)(B) of the Act, and that a patent infringement action was initiated against you in United States District Court for the Western District of Missouri (Bayer AG, Bayer Corporation, and Pfizer, Inc. vs. Martec Pharmaceutical, Inc. and Martec Scientific, Inc., Civil Action No. 98-1310-CV-W-BC). You subsequently informed the agency that Martec entered into a settlement agreement with the plaintiffs with respect to the patent infringement action, and that Martec also entered into a license agreement with Pfizer Inc. regarding Nifedipine Extended-release Tablets USP.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Nifedipine Extended-release Tablets USP, 90 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Procardia XL® Tablets, 90 mg, Pfizer Laboratories). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in 1000 mL of 1.25% of Tween 80, at 37°C using USP Apparatus I (Basket) at 100 rpm. The test product should meet the following "interim" specifications:

Time (hours)	Range
1	-----------
4	----------
12	-------
24	-------

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications or if the proposed final specifications are tighter than the "interim" specifications. In all other instances, the data should be submitted in the form of a Prior Approval Supplement.

With respect to 180-day generic drug exclusivity, we note that Martec Scientific, Inc. (Martec) was the first ANDA applicant to submit a substantially complete ANDA containing paragraph IV certifications to the patents listed in the Orange Book for Pfizer's Procardia XL Tablets. Therefore, with this approval, Martec is eligible for 180-days of market exclusivity with respect to the '446 patent for Nifedipine Extended-release Tablets USP, 90 mg. Such exclusivity will begin to run from the date Martec begins commercial marketing of the drug product. Alternatively, in the absence of commercial marketing, the exclusivity will begin from the date of a decision of an appellate court finding the patent invalid or not infringed; whichever event occurs earlier [Section 505(j)(5)(B)(iv)].

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commenced commercial marketing of this product, or the date of the appellate decision of the court holding the relevant patent invalid, unenforceable or not infringed.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and

Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

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

cc: ANDA 75-414
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205
HFD-610/Orange Book Staff

Endorsements:
HFD-647/U.Venkataram for S.Basaran/10/17/03
HFD-647/U.Venkataram/10/17/03
HFD-617/S.Shepperson/10/17/03
HFD-613/A.Vezza/10/20/03
HFD-613/L.Golson/10/20/03

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F/T by rad10/16/03

APPROVAL