CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

89884

APPROVAL LETTER

ANDA 89-884 (0.2 mg/hour)
89-885 (0.4 mg/hour)
89-886 (0.6 mg/hour)

October 30, 1998

Hercon Laboratories Corporation
Attention: Thomas J. Atkins, Ph.D.
P.O. Box 786
York, PA 17405

Dear Sir:

This is in reference to your abbreviated new drug applications dated November 12, 1987, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Nitroglycerin Transdermal Systems, 0.2 mg/hr, 0.4 mg/hr, and 0.6 mg/hr.

Reference is also made to your amendments dated April 27, 1993; October 10, and November 22, 1996; November 3, 1997; and June 2, June 26, July 9, August 17, September 11, and October 8, 1998.

We have completed the review of these abbreviated applications and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Nitroglycerin Transdermal Systems, 0.2 mg/hr, 0.4 mg/hr, and 0.6 mg/hr, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Transderm-Nitro®, 0.2 mg/hr, 0.4 mg/hr, and 0.6 mg/hr, respectively, of Novartis Pharmaceuticals Corp.).

Your dissolution testing should be incorporated into the stability and control program. The dissolution testing should be conducted in 500 mL of water at 32°C using paddle over disk at 50 rpm. The test products should meet the following interim dissolution specifications:

Time	Limits
0.25 hr	
0.5 hr	
1.0 hr	
4.0 hr	

The interim release rate specifications should be finalized by submitting supplemental applications containing dissolution data for the first three production size batches of each strength

produced post-approval. The supplemental applications should be submitted under 21 CFR 314.70(c)(1) when there are no revisions to the interim specifications or when the final specifications are tighter than the interim specifications. In all other instances the supplemental applications should be submitted under 21 CFR 314.70(b)(2)(ii).

The Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (The "Orange" Book), 18th edition, reveals that the listed drug referenced in your applications is subject to a period of patent protection which expires on December 4, 2001 (patents 4,812,313; 4,954,344, and 4,849,226). In accord with 21 CFR 314.94(a)(12)(vi), Hercon is not required to submit an amended patent certification to these patents.

Under 21 CFR 314.70, certain changes in the conditions described in these abbreviated applications require approved supplemental applications before the change may be made.

Post-marketing reporting requirements for these abbreviated applications 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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-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 FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research