

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number 74941

Trade Name Diltiazem Hydrochloride Injection 5mg/ml

Generic Name Diltiazem Hydrochloride Injection 5mg/ml

Sponsor Abbott Laboratories

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APPLICATION 74941

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				
Approvable Letter				
Final Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)	X			
Administrative Document(s)	X			
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Application Number 74941

APPROVAL LETTER

ANDA 74-941

APR 15 1999

Abbott Laboratories
Hospital Products Division
Attention: Thomas P. Sampogna
200 Abbott Park Road, D389, AP30
Abbott Park, IL 60064-3537

Dear Sir:

This is in reference to your abbreviated new drug application dated August 13, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Diltiazem Hydrochloride Injection, 5 mg/mL (5 mL and 10 mL single-dose vials).

Reference is also made to your amendments dated October 7, 1997 and January 22, and March 18, 1998.

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 Diltiazem Hydrochloride Injection, 5 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Cardizem® Injectable, 5 mg/mL, of Hoechst Marion Roussel Inc.).

Under 21 CFR 314.70, 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. 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-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

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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-240) 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