

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-849 / S-011

***Trade Name:* REV- EYES**

***Generic Name:* Dapiprazole hydrochloride ophthalmic solution**

***Sponsor:* Angelini Pharmaceuticals**

***Approval Date:* April 17, 2002**

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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	

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APPROVAL LETTER



NDA 19-849/S-011

Angelini Pharmaceuticals, Inc.
Attention: William M. Troetel, Ph.D.
Regulatory Consultant
70 Grand Avenue
River Edge, NJ 07661

Dear Dr. Troetel:

Please refer to your supplemental new drug application dated November 21, 2001, received November 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REV-EYES (dapiprazole hydrochloride ophthalmic solution) 0.5%.

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for an alternate analytical testing site.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Linda Ng
4/17/02 03:03:21 PM

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APPLICATION NUMBER:

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CHEMISTRY REVIEW(S)

Chemistry Review: # 1	1. Division: HFD-550	2. NDA Number: 19-849
3. Name and Address of Applicant: Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661		4. Supplement(s): Number: SCM-011 Date(s): November 21, 2001
5. Name of Drug: REV-EYES		6. Nonproprietary name: Dapiprazole Hydrochloride
7. Supplement Provides for alternative analytical testing laboratory site. CBE-30		8. Amendment(s): None
9. Pharmacological Category: Alpha-adrenergic receptor blocker.	10. How Dispensed: R _x	11. Related Documents: 19-849 SCM-012, November 21, 2001
12. Dosage Form: Ophthalmic Solution.	13. Potency: dapiprazole hydrochloride 0.5%	
14. Chemical Name and Structure: See USAN Dapiprazole hydrochloride, C ₁₉ H ₂₇ N ₅ •HCl, Mol. Wt. 361.93 5,6,7,8-tetrahydro-3-[2-(4- <i>o</i> .tolyl-1-piperazinyl)ethyl]- <i>s</i> -triazolo[4,3- <i>a</i>]pyridine hydrochloride.		
15. Comments: This application complies with the four recommendations set by the agency in the " Guidance for Industry: PAC-ATLS: Post-Approval Changes - Analytical Testing Laboratory Sites" dated April 1998. The proposed alternate analytical site, _____ as submitted to EES for inspection on December 4, 2001 and was recommended as acceptable by the OC on March 18, 2002 (see attached report).		
16. Conclusions and Recommendations: From the viewpoint of CMC, this supplement is recommended for approval.		
17. Name: Libaniel Rodriguez, Chemist	Signature:	Date:
18. Concurrence: Linda Ng, Chemistry Team Leader	Signature:	Date:

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/s/

Libaniel Rodriguez
4/2/02 11:27:32 AM
CHEMIST

Linda Ng
4/3/02 01:43:36 PM
CHEMIST
PM to prepare AP letter