CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-849 / S-012

Trade Name: **REV- EYES**

Generic Name: **Dapiprazole hydrochloride ophthalmic solution**

Sponsor: **Angelini Pharmaceuticals**

Approval Date: **April 17, 2002**

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APPLICATION NUMBER:

19-849 / S-012

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-849/S-012

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 Effected 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 03:13:28 PM

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APPLICATION NUMBER:

19-849 / S-012

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-012 **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-011, November 21, 2001
12. Dosage Form: Ophthalmic Solution.	**13. Potency:** dapiprazole hydrochloride 0.5%	

14. Chemical Name and Structure: See USAN

Dapiprazole hydrochloride, $C_{19}H_{27}N_5 \bullet HCl$, Mol. Wt. 361.93

5,6,7,8-tetrahydro-3-[2-(4-*o*.tolyl-1-piperazinyl)ethyl]-*s*-triazolo[4,3-a]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, [redacted], was submitted to EES for inspection on December 8, 2001 and was recommended as acceptable by the OC on March 29, 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:**

ATTACHMENT

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application	: NDA 19849/012	Sponsor:	ANGELINI PHARMS
Org Code	: 550		70 GRAND AVE
Priority	: 1P		RIVER EDGE, NJ 07661
Stamp Date	: 26-NOV-2001	Brand Name :	REV-EYES
PDUFA Date	: 26-MAY-2002	Estab. Name:	
Action Goal	:	Generic Name:	DAPIPRAZOLE HYDROCHLORIDE
District Goal:	21-APR-2002	Dosage Form:	(DROPS)
		Strength :	0.5%

FDA Contacts:	M. PUGLISI	Project Manager (HFD-550)	301-827-2090
	L. RODRIGUEZ	Review Chemist (HFD-830)	301-827-2069
	L. NG	Team Leader (HFD-830)	301-827-2511

--Overall Recommendation:

Establishment : [redacted]

DMF No: AADA:

Responsibilities:

Profile :	CTL	OAI Status:	NONE
Last Milestone:	INSPECTION PERFORMED		
Milestone Date:	29-MAR-02		

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/s/

Libaniel Rodriguez
4/2/02 11:31:14 AM
CHEMIST

Linda Ng
4/3/02 01:47:26 PM
CHEMIST
PM to prepare AP letter