

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

64-134

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA #: 64-134 **FIRM:** Bausch & Lomb

DRUG PRODUCT: Tobramycin and Dexamethasone Ophthalmic Suspension
USP, 0.3%/0.1%

DOSAGE: See above **STRENGTH:** See above

CAMP STATEMENT/EIR UPDATE STATUS: Pending

BIO STUDY: Acceptable (6/17/99)

METHOD VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
Not requested (USP drug)

STABILITY - (ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION): The container/closure system used in the stability study is the same as those described in the container section.

LABELING: Acceptable (9/13/99)

STERILIZATION VALIDATION:
Acceptable 11/27/96; see also reviews done by C. Vincent 5/10/99 and L. Ensor 9/10/99.

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?): See below

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):

The maximum intended production batch size is
Previously two exhibit batches were made for 2.5 and 5.0 mL sizes. In Amendment 12/10/98, data for a new exhibit batch #01583 is provided for 5 mL fill (filled).

PROPOSED PRODUCTION BATCH - (MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?): See above

Specifications for active ingredient: Under #23A

Specifications for the finished product: Under #28 and #29

CHEMIST: Maria C. Shih *M.C. Shih* **DATE:** 8/20/99 *9/23/99*

SUPERVISOR: R. Adams *R.C. Adams* **DATE:** 8/23/99 *7/27/99*

RECORD OF TELEPHONE CONVERSATION

<p>Dr. Lynne Ensor initiated a telecon with David Desris regarding the amendment (12/10/98) submitted for the AADA 64-134. Issues regarding the sterility assurance of the product were clarified:</p> <p>1. will the product be commercially produced on</p> <p>response: '</p> <p>2. Please explain the media fill result contamination rates (hat were observed.</p> <p>response: David will fax me today or tomorrow information regarding the investigation into and the identification of the contaminants obtained from these grossly contaminated media fills on . He will also follow this up with a hard copy of the documentation submitted to the document room.</p> <p>David indicated that Marc Anderson already is routing an approvals package within the agency.</p>	DATE SEPTEMBER 7, 1999
	ANDA NUMBER 64-134
	IND NUMBER
	TELECON
	INITIATED BY SPONSOR X FDA
	PRODUCT NAME Tobramycin & Dexamethasone Ophthalmic Suspension, USP, 0.3%/0.1%
	FIRM NAME BAUSCH & LOMB PHARMACEUTICALS, TAMPA, FL
	NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD DAVID DESRIS, R.P h. Manager, Regulatory Affairs
	TELEPHONE NUMBER 1(813) 975-7775
SIGNATURE <i>Lynne Ensor</i> 9/7/99	

Drafted by L. Ensor 9/7/99

TO (Division/Office) <i>CDR V - Mary Jane Williams, Director</i> <i>HFD-550 / Division of Anti-Biologics / Ophthalmic / R. Chambers</i>	FROM: <i>CDR HFD-615 Office of Generic Drugs</i>
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DATE: <i>1/25/99</i>	IND NO. _____	NDA NO. <i>64-134</i>	TYPE OF DOCUMENT <i>Clinical "Bio" Study</i>	DATE OF DOCUMENT <i>December 10, 1998</i>
OF DRUG <i>Tobramycin & an effusive Ophthalmic Suspension, 0.3% / 0.1%</i>		PRIORITY CONSIDERATION <i>High</i>	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE <i>3/25/99 (90 days)</i>

NAME OF FIRM *Bausch & Lomb*

REASON FOR REQUEST

I. GENERAL

- | | | |
|--|--|---|
| <input type="checkbox"/> NEW PROTOCOL
<input type="checkbox"/> PROGRESS REPORT
<input type="checkbox"/> NEW CORRESPONDENCE
<input type="checkbox"/> DRUG ADVERTISING
<input type="checkbox"/> ADVERSE REACTION REPORT
<input type="checkbox"/> MANUFACTURING CHANGE/ADDITION
<input type="checkbox"/> MEETING PLANNED BY _____ | <input type="checkbox"/> PRE NDA MEETING
<input type="checkbox"/> END OF PHASE II MEETING
<input type="checkbox"/> RESUBMISSION
<input type="checkbox"/> SAFETY/EFFICACY
<input type="checkbox"/> PAPER NDA
<input type="checkbox"/> CONTROL SUPPLEMENT | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER
<input type="checkbox"/> FINAL PRINTED LABELING
<input type="checkbox"/> LABELING REVISION
<input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE
<input type="checkbox"/> FORMULATIVE REVIEW
<input checked="" type="checkbox"/> OTHER (specify below) |
|--|--|---|

II. BIOMETRICS

- | STATISTICAL EVALUATION BRANCH | STATISTICAL APPLICATION BRANCH |
|--|--|
| <input type="checkbox"/> TYPE A OR B NDA REVIEW
<input type="checkbox"/> END OF PHASE II MEETING
<input type="checkbox"/> CONTROLLED STUDIES
<input type="checkbox"/> PROTOCOL REVIEW
<input type="checkbox"/> OTHER | <input type="checkbox"/> CHEMISTRY
<input type="checkbox"/> PHARMACOLOGY
<input type="checkbox"/> BIOPHARMACEUTICS
<input type="checkbox"/> OTHER |

III. BIOPHARMACEUTICS

- | | |
|---|--|
| <input type="checkbox"/> DISSOLUTION
<input type="checkbox"/> PROTOCOL - BIOPHARMACEUTICS
<input type="checkbox"/> IN-VIVO WAIVER REQUEST | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE
<input type="checkbox"/> BIOAVAILABILITY STUDIES
<input type="checkbox"/> PHASE IV STUDIES |
|---|--|

IV. DRUG EXPERIENCE

- | | |
|---|--|
| <input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
<input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
<input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below)
<input type="checkbox"/> COMPARATIVE RISK ASSESSEMENT ON GENERIC DRUG GROUP | <input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
<input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE
POISON RISK ANALYSIS |
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V. SCIENTIFIC INVESTIGATIONS

- | | |
|-----------------------------------|--------------------------------------|
| <input type="checkbox"/> CLINICAL | <input type="checkbox"/> PRECLINICAL |
|-----------------------------------|--------------------------------------|

COMMENTS/SPECIAL INSTRUCTIONS (Attach additional sheets if necessary) *The firm has completed a clinical bioequivalence between the Reference Listed Drug (Tobrex Rx) and their proposed drug product. Please review and comment on the study (BLP 287402) (See Sections 13 & 14 of this Submission) Please provide an electronic transfer and return!*

HARVEY A. GREENBERG, R.Ph.

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(301) 827-5862
 FAX (301) 594-1174

SIGNATURE OF REQUESTER <i>Harvey A. Greenberg 827-5713</i>	METHOD OF DELIVERY (Check one) <input type="checkbox"/> MAIL <input type="checkbox"/> HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER