CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-358

ADMINISTRATIVE DOCUMENTS

APPROVAL SUMMARY PACKAGE

ANDA NUMBER: 75-358

FIRM: Bausch and Lomb Pharmaceuticals (BLP)

DOSAGE FORM: Inhalation Solution

STRENGTH: 0.083%

DRUG: Albuterol Sulfate Inhalation Solution

cGMP STATEMENT/EIR UPDATED STATUS: Acceptable 05/24/99.

BIO STUDY: Acceptable (waiver is granted) 07/23/98.

METHODS VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
Acceptable per 07/30/99.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?
Containers used in the stability studies are identical to those listed in container section (3 mL vials with an overwrap).

Expiration dating period is 24 months for the drug product.

LABELING:
Satisfactory per Watkins' review dated 08/18/99..

STERILIZATION VALIDATION (IF APPLICABLE):
Acceptable per 10/20/99(vol. 3.1).

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.?):

Production Batches	Bio/stability batch Lot#953171

NDS Source: DMF Holder: DMF #:

Recent DMF updates	Review	Status
03/01/00	Yes	IR (minor issue)

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

Production Batches	Bio/stability batch Lot#953171
kg	

The manufacture process for stability batches are the same as those for the commercial production.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?

The manufacture process for stability batches are the same as those for the commercial production.

Bing Cai
Review Chemist

Mike Smela
Team Leader

Division of Chemistry I
OGD/CDER
10/15/99

Endorsements:

3/21/00

M Smela
3/22/00

E L E C T R O N I C M A I L M E S S A G E

Date: 02-Feb-2000 12:06pm EST
From: Michael Smela
SMELA
Dept: HFD-625 MPN2 E236
Tel No: 301-827-5848 FAX 301-594-0180

TO: Mary Fanning (FANNINGM)
TO: Michelle Dillahunt (DILLAHUNTM)
TO: Guiragos Poochikian (POOCHIKIAN)

CC: Rashmikant Patel (PATELR)
CC: Allen Rudman (RUDMANA)
CC: Doug Sporn (SPORND)
CC: Bing Cai (CAIB)

Subject: Safety Consult for ANDA 75358

Mary....Michelle will be preparing a consult package for you. This email is for background information. The product is Bausch and Lomb Albuterol Inhalation Solution (0.083%) packaged in with a protective pouch. We required the applicant to demonstrate that the solution was free of packaging contaminants the level. They were unable to do so. Instead, they have found their duct contaminated with about of based on a validated analytical method. The source of the contaminant is the protective pouch. Dr. Rudman consulted with the pulmonary division as to whether this level of contamination is of concern. In an email dated 11/24/99 from Virgil Whitehurst of HFD570, we were advised that an applicant found to have a product contaminated with the same compound at was advised that it is a safety issue and safety data are needed. Based on this, we NAed the ANDA on 12/10/99 saying B&L must either qualify a pouch that does not contaminate or provide safety data for at the level found in their product. B & L has responded by amendment dated 1/21/00 with some safety references. They also declare that
s currently marketed with a similar level of contamination. Data are provided using a validated method for 3 lots of as rec'd from the marketplace with contamination at information is provided that uses a similar overwrap as B&L is proposing. B&L states this information is sufficient to approve their ANDA. A consult review of ANDA approvability is requested.

Michelle...Please prepare a consult package for Dr. Fanning consisting of:
12/10/99 NA Letter
11/24/99 and 1/21/00 amendments
12/15/99 Tcon
Whitehurst 11/24/99 Email

itionally,since this is the only outstanding issue for this ANDA, please add it to the approval matrix so it may be tracked.

Guirag....If you would like a copy of the B&L info for your use, please let Michelle know.

Thanks all...Mike

E L E C T R O N I C M A I L M E S S A G E

Sensitivity: COMPANY CONFIDENTIAL

Date: 24-Nov-1999 12:38pm EST
From: Virgil Whitehurst
WHITEHURST
Dept: HFD-570 PKLN 10B45
Tel No: 301-827-1050 FAX 301-827-1271

TO: Allen Rudman (RUDMANA)
TO: Guiragos Poochikian (POOCHIKIAN)
TO: Vibhakar J. Shah (SHAHVJ)

Subject:

Alan:
Dr Poochikan asked me to E-mail you concerning the safety of as a leachable.
The following comment was included in our letter to Dey Labs regarding as a leachable in the drug product
The level of in each vial of drug product was approximately

Comment 24.
If it remains your intention to utilize the foil overwrap from which leached into the drug solution, you will need to alify i. If there are insufficient data available in ..e literature, perform a 90-day inhalation study to qualify

This study should include histopathological evaluation of a complete battery of tissues. In addition, because the structure of suggests that it may react with DNA, you must evaluate its genotoxicity. A minimum evaluation may include an Ames test and a mouse lymphoma TK assay.

If you need aditional safety information/data concerning , please let us know.
Virgil

RECORD OF TELEPHONE CONVERSATION

This telecon is in response to a fax received on December 13, 1999 from Bausch & Lomb. The sponsor requested a telecon to discuss the December 10, 1999 minor amendment received for ANDA 75-358. Specifically, the firm would like to discuss:

The information needed to demonstrate the safety of

The information required to qualify a new pouch material, should this be necessary.

Mr. Mike Smela informed the firm that the November 24,1999 amendment stating that is present in another inhalation product, Solution, had not been reviewed when the last deficiency was sent to the firm. Mr. Smela informed the firm that they could state that the Agency should approve their product because a similar product has the same contaminant. The firm would have to submit complete information, such as lot numbers, expiry date, storage conditions, validation summary, chromatograms and data. OGD will still have to consult with the pulmonary division. We do not know how the pulmonary division will respond.

Mr. Smela informed the firm of their two options;

1. Provide a safety information package for d.

2. Obtain a new overwrap/pouch system that does not contaminate the product.

Mr. Smela informed the firm that if they could provide absolute documentation that the overwrap/pouch is being used for another approved inhalation product, they would not need to submit an exhibit batch.

V:\FIRMSAM\BAUSCH\TELECONS\75358TCON2.DOC

DATE
December 15, 1999

ANDA NUMBER
75-358

IND NUMBER

TELECON

INITIATED BY

SPONSOR X

FDA

PRODUCT NAME
Albuterol Sulfate Inhalation Solution, 0.083%

FIRM NAME
Bausch & Lomb

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Mike Brubaker,
Don Chmielewski,
Joe Hawkins,
Ramesh Krisnamoorthy,
Jim Huang

TELEPHONE NUMBER
(813) 975-7700
Ext #7678

SIGNATURE
M.Dillahunt 12/16/99
M.Smela
12/16/99

CC: ANDA 75-358
Chem Div I, T-con Notebook

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book? Orange Book: Albuterol Sulfate Solution Inhalation Name used: Albuterol Sulfate Inhalation Solution	X		
If not USP, has the product name been proposed in the PF?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?	X		
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	

APPROVAL SUMMARY
REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-358 Date of Submission: August 12, 1999
Applicant's Name: Bausch & Lomb Pharmaceuticals, Inc.
Product Name: Albuterol Sulfate Inhalation Solution,0.083%(base)

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval): Do you have 12 Final Printed Labels and Labeling? Yes
Unit Dose Container Label: (3 mL) Satisfactory as of June 9, 1999 submission.
Foil Pouch: (28 x 3 mL and 60 x 3 mL) Satisfactory as of June 9, 1999 submission.
Unit Dose Carton Label: (28 x 3 mL and 60 x 3 mL) Satisfactory as of August 12, 1999 submission.

Professional Package Insert Labeling: Satisfactory as of June 9, 1999 submission.

Patient Package Insert Labeling: Satisfactory as of June 9, 1999 submission

BASIS OF APPROVAL:
Was this approval based upon a petition? No
What is the RLD on the 356(h) form: Ventolin®

NDA Number: 19-773/S-010
NDA Drug Name: Albuterol Sulfate Inhalation Solution 0.083%
NDA Firm: Glaxo-Wellcome

Date of Approval of NDA Insert and supplement #: Sept 18, 1998
Has this been verified by the MIS system for the NDA? Yes
Was this approval based upon an OGD labeling guidance? No

Basis of Approval for the Container Labels: Approved Ventolin® container labeling.
Basis of Approval for the Carton Labeling: Approved Ventolin® carton labeling.

Labeling (continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?			X
Does USP have labeling recommendations? If any, does ANDA meet them?			X
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	X		
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			X
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T ½ and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.		X	

NOTES/QUESTIONS TO THE CHEMIST:

FOR THE RECORD:

1. Review based on the labeling of the reference listed drug (Ventolin®; NDA#19-773/S-010; Approved September 18, 1998; Revised May 1998).

2. Patent/ Exclusivities :

   There are no patents or exclusivities that pertain to this drug product.

3. Storage/ Dispensing Conditions :
   NDA: Store in refrigerator between 2°C and 8°C (36°F and 46°F). Protect from light. May be held at room temperature for up to 2 weeks before use. Discard if solution becomes discolored.
   ANDA: Same as NDA

4. Product Line :

   INNOVATOR: 3 mL each/prediluted/foil pouch of 25/25 count carton.
   APPLICANT:3 mL each/prediluted/foil pouch of 28 and 60/2 and 60 count carton.

5. The solution has been accurately described in the DESCRIPTION section. See page 961, Vol. 1.4. It is described as a clear, colorless solution.

6. Inactive Ingredients :

   The inactive ingredients as stated in the DESCRIPTION section appear to be correct. See page 84, Vol. 1.1.

7. All manufacturing is performed by Bausch & Lomb. Outside firms are utilized for testing only. See Page 198, Vol. 1.1.

8. Container/ Closure :

   The product will be packaged in a 3 mL fill size Resin in foil pouches and cartoned. See Page 897, Vol. 1.4.

Date of Review: August 17, 1999
Date of Submission: August 12, 1999

Reviewer: [signature] Date: 8/17/99

Team Leader: [signature] Date: 8/18/1999

cc: [signature] 8/17/99

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food & Drug Administration

Memorandum

Southeast Regional Laboratory

Date July 29, 1999

From NDA/ANDA Coordinator, Chemistry Branch
Southeast Regional Laboratory (HFR-SE660)

Subject ANDA 75-358 (Albuterol Sulfate Inhalation Solution)

To Bing Cai, PhD, Reviewing Chemist
Center for Drugs and Evaluation Research, (HFD-625)

Firm: Bausch and Lomb Pharmaceuticals
8500 Hidden River Parkway
Tampa, FL 33637

Analyst Luis Burgos has completed the subject ANDA method validation. No problems were encountered with the methods tested and his comments on the related substances test is attached. The firm did not provide any standards in order to validate the related substances. The methods tested were found to be suitable for regulatory purposes. His worksheet and all pertinent information are attached.

If you need any further information, you may contact me at (404) 253-1200 extension 5297 or by banyan.

Cheryl L. Love

CC:

Albuterol Sulfate
Solution for Inhalation, 0.083%
ANDA #75-358
Reviewer: Moheb H. Makary
WP No. 75358W.498

Bausch & Lomb Pharmaceuticals
Tempa, FL
Submission Date:
April 14, 1998

Review of a Wavier Request

The firm is requesting a waiver of *in vivo* bioequivalence requirements for its albuterol sulfate USP in inhalation solution 0.083%, based on CFR 320.22 (b)(3). The reference listed product is Ventolin Nebules® Inhalation Solution, 0.083%, manufactured by Allen & Hansburys Division of Glaxo, Inc. The product is indicated for the relief of bronchospasm in patients with reversible obstructive airway disease and acute attacks of bronchospasm.

Comparative formulas for the test and reference products in support of the waiver request are given in Table 1, below:

TABLE 1 - COMPARATIVE FORMULATIONS

Ingredient	Amount (mg)	
	B&LP	Ventolin®
Albuterol Sulfate		
Sodium Chloride,		
Purified Water,		
Sulfuric Acid,	adjust pH (target	adjust pH (between

* Equivalent to 0.083% Albuterol free base

Comment:

The firm has met the criteria for waiver of the *in vivo* bioequivalence study requirements for its albuterol sulfate inhalation solution, 0.083%, per 21 CFR 320.22 (b)(3), as follows:

(1) The product is a solution for inhalation.

(2) It contains an active ingredient in the same dosage form as the listed reference product.

(3) It contains no inactive ingredient or other change in formulation from the drug product that is the subject of the approved full new drug application that may significantly affect absorption of the active drug ingredient or active moiety.

Recommendation:

1. The waiver of *in vivo* bioequivalence study requirements for Albuterol Sulfate Inhalation Solution, 0.083%, sponsored by Bausch & Lomb Pharmaceuticals, Inc., is granted by the Division of Bioequivalence per 21 CFR 320.22 (b)(3). The test product is therefore deemed bioequivalent to Ventolin Nebules® Inhalation Solution, 0.083%, manufactured by Allen & Hansburys Division of Glaxo, Inc.

2. From the bioequivalence viewpoint, the firm has met the bioequivalence requirements and the ANDA #75-358 is acceptable.

The firm should be informed of the above recommendation.

Moheb H. Makary

Moheb H. Makary, Ph.D.
Division of Bioequivalence
Review Branch III

RD INITIALLED BDAVIT BMD 7/22/98
FT INITIALLED BDAVIT Barbara M Davit Date: 7/24/98

Concur: Dale P. Conner Date: 7/23/98
Dale Conner, Pharm.D.
Director
Division of Bioequivalence

File

Application: **ANDA 75358/000**
Stamp: **15-APR-1998** Regulatory Due:
Applicant: **BAUSCH AND LOMB**
8500 HIDDEN RIVER PKY
TAMPA, FL 33637

Priority: Org Code: **600**
Action Goal: District Goal: **15-JUN-1999**
Brand Name:
Established Name: **ALBUTEROL SULFATE**
Generic Name:
Dosage Form: **SOL (SOLUTION)**
Strength: **0.083%**

FDA Contacts: **S. OKEEFE (HFD-617) 301-827-5848 , Project Manager**
M. SMELA JR (HFD-625) 301-827-5848 , Team Leader

Overall Recommendation:

Establishment:
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **13-MAY-1998**
Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment: **1052807**
BAUSCH AND LOMB PHARMACEUT
8500 HIDDEN RIVER PKY
TAMPA, FL 33637
DMF No:
AADA No:

Profile: **LIQ** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **13-MAY-1998**
Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment:
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **13-MAY-1998**
Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment: **1419992**
DMF No:

AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **13-MAY-1998**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment: [illegible]

DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **13-MAY-1998**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-358 Date of Submission: April 14, 1998

Applicant's Name: Bausch & Lomb Pharmaceuticals, Inc.

Established Name: Albuterol Sulfate Inhalation Solution, 0.083% (base)

Labeling Deficiencies:

1. UNIT DOSE CONTAINER (3 mL)

   We note you have not submitted draft labels for the 3 mL unit dose container. Please submit for review and comment.

2. FOIL POUCH (28 x 3 mL and 60 x 3 mL)

   a. Revise the "Each mL contains..." statement to read as follows: Each milliliter contains albuterol sulfate equivalent to 0.83 mg of albuterol.

   b. On the principle display panel include the following statement:
      Prediluted with Normal Saline.

   c. Include the following statement:
      Equivalent to 0.5 ml albuterol sulfate 0.5%*
      diluted to 3 ml with normal saline
      *Potency expressed as albuterol.

   d. Revise to read:

      Usual Dosage: See package insert...

3. CARTON (28 x 3 mL and 60 x 3 mL

   See comments under FOIL POUCH.

4. INSERT

We note you have not utilized the most current labeling of the reference listed drug as your model for the insert labeling. Revise your insert to be in accord with the enclosed copy of the most recently approved labeling for Ventolin® (Approved October 30, 1997, Revised September 1997). In addition, revise the following:

a. DESCRIPTION

i. Chemical name- Capitalize the "b" in "Butylamino".

ii. Revise the molecular weight to read "576.71" rather than "576.7" to be in accord with USP 23.

Please revise your unit dose container labels, foil pouch, carton and insert labeling, as instructed above, and submit draft labels and labeling.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosure:
Ventolin® labeling

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? No
If no; list why: Draft labeling only.

Unit Dose Container Label:

Foil Pouch:

Unit Dose Carton Label:

Professional Package Insert Labeling:

Patient Package Insert Labeling:

Revisions needed post-approval:

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Ventolin®

NDA Number: 19-773

NDA Drug Name: Albuterol Sulfate Inhalation Solution 0.083%

NDA Firm: Glaxo-Wellcome

Date of Approval of NDA Insert and supplement #: October 30,1997
S-009

Has this been verified by the MIS system for the NDA?
Yes

Was this approval based upon an OGD labeling guidance? No

If yes, give date of labeling guidance:

Basis of Approval for the Container Labels: Approved Ventolin® container labeling.

Basis of Approval for the Carton Labeling: Approved Ventolin® carton labeling.

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book? Orange Book: Albuterol Sulfate Solution Inhalation Name used: Albuterol Sulfate Inhalation Solution	X		
If not USP, has the product name been proposed in the PF?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?	X		
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	

Labeling (continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?			X
Does USP have labeling recommendations? If any, does ANDA meet them?			X
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	X		
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			X
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.		X	

NOTES/QUESTIONS TO THE CHEMIST:

FOR THE RECORD:

1. Review based on the labeling of the reference listed drug (Ventolin®; Approved October 30, 1997; Revised September 1997).

2. Patent/ Exclusivities :

   There are no patents or exclusivities that pertain to this drug product.

3. Storage/ Dispensing Conditions :

   NDA: Store in refrigerator between 2°C and 8°C (36°F and 46°F). Protect from light. May be held at room temperature for up to 2 weeks before use. Discard if solution becomes discolored.

   ANDA: Same as NDA

   USP: Not USP or NF

4. Product Line :

   INNOVATOR: 3 mL each/prediluted/foil pouch of 25/ 25 count carton.

   APPLICANT: 3 mL each/prediluted/foil pouch of 28 and 60/ 28 and 60 count carton.

5. The solution has been accurately described in the DESCRIPTION section. See page 961, Vol. 1.4. It is described as a clear, colorless solution.

6. Inactive Ingredients :

   The inactive ingredients as stated in the DESCRIPTION section appear to be correct. See page 84, Vol. 1.1.

7. All manufacturing is performed by Bausch & Lomb. Outside firms are utilized for testing only. See Page 198, Vol. 1.1.

8. Container/ Closure :

   The product will be packaged in a 3 mL fill size Resin in foil pouches and cartoned. See Page 897, Vol. 1.4.

Date of Review: May 20, 1998
Date of Submission: April 14, 1998

Reviewer: [illegible] Date: 5/27/98

Team Leader: John D. Grace Date: 5/27/98

cc:

rs&rev\75358na1.1

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

NDA Number: 75-358 **Date of Submission: November 6, 1998**

Applicant's Name: Bausch & Lomb Pharmaceuticals, Inc.

Established Name: Albuterol Sulfate Inhalation Solution, 0.083% (base)

Labeling Deficiencies:

1. UNIT DOSE CONTAINER (3 mL)

   Satisfactory in draft.

2. FOIL POUCH (28 x 3 mL and 60 x 3 mL)

   a. Revise "euivalent" to read "equivalent" in the Each milliliter contains ... statement.

3. CARTON (28 x 3 mL and 60 x 3 mL

   See comments under FOIL POUCH.

4. INSERT

   a. TITLE

      We encourage the inclusion of "℞ only" in this section.

   b. CLINICAL PHARMACOLOGY

      i. Revise the first sentence of paragraph two of this section to read as follows:

         ...(ATP) to cyclic-3′5′-adenosine monophosphate (cyclic AMP).

   c. PRECAUTIONS

      i. Carcinogenesis, Mutagenesis, Impairment of Fertility

         Revise the first sentence of this subsection

to read as follows:

...50 mg/kg (approximately 2, 8, and 40 times...basis or approximately 3/5, 3 and 150 times...

ii. Pregnancy: Teratogenic Effects: Pregnancy Category C

Revise the first sentence of paragraph one of this subsection to read as follows:

...subcutaneous doses of 0.025,...

d. ADVERSE REACTIONS

i. Include the "Percent Incidence of Adverse Reactions" Table to match Ventolin®(Approved September 18, 1998; Revised May 1998).

ii. Revise the last paragraph of this section to read as follows:

Cases of urticaria, angioedema, rash, bronchospasm, hoarseness, oropharyngeal edema, and arrhythmias (including atrial fibrillation, supraventricular tachycardia, extrasystoles) have been reported after the use of albuterol sulfate inhalation solution.

e. OVERDOSAGE

i. Revise the second sentence of paragraph three of this section to read as follows:

...,the subcutaneous median lethal...

ii. Revise the third sentence of paragraph three of this section to read as follows:

In small young rats, the subcutaneous median lethal...

f. DOSAGE AND ADMINISTRATION

Bold the following sentence:

Adults and Children 2 to 12 Years of Age:

g. HOW SUPPLIED

Revise your HOW SUPPLIED statement to include reference to the foil pouch.

Please revise your unit dose container labels, foil pouch, carton and insert labeling, as instructed above, and submit 12 copies of final printed container labels, along with 12 copies each of final printed foil pouch, carton and insert labeling or draft if you prefer.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

Labeling (continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult: Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?			X
Does USP have labeling recommendations? If any, does ANDA meet them?			X
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	X		
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			X
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T ½ and state study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.		X	

NOTES/QUESTIONS TO THE CHEMIST:

FOR THE RECORD:

1. Review based on the labeling of the reference listed drug (Ventolin®; NDA#19-773/S-010; Approved September 18, 1998; Revised May 1998).

2. Patent/ Exclusivities :

   There are no patents or exclusivities that pertain to this drug product.

3. Storage/ Dispensing Conditions :

   NDA: Store in refrigerator between 2°C and 8°C (36°F and 46°F). Protect from light. May be held at room temperature for up to 2 weeks before use. Discard if solution becomes discolored.

   ANDA: Same as NDA

   USP: Not USP or NF

4. Product Line :

   INNOVATOR: 3 mL each/prediluted/foil pouch of 25/ 25 count carton.

   APPLICANT: 3 mL each/prediluted/foil pouch of 28 and 60/ 28 and 60 count carton.

5. The solution has been accurately described in the DESCRIPTION section. See page 961, Vol. 1.4. It is described as a clear, colorless solution.

6. Inactive Ingredients :

   The inactive ingredients as stated in the DESCRIPTION section appear to be correct. See page 84, Vol. 1.1.

7. All manufacturing is performed by Bausch & Lomb. Outside firms are utilized for testing only. See Page 198, Vol. 1.1.

8. Container/ Closure :

   The product will be packaged in a 3 mL fill size Resin in foil pouches and cartoned. See Page 897, Vol. 1.4.

Date of Review: November 18, 1998
Date of Submission: November 6, 1998

Reviewer: JWatts Date: 12/2/98

Team Leader: Date:

John D. Grace 12/2/98

cc:

(O CC)
JSCH\LTRS&REV\75358NA2.L

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-358 **Date of Submission: November 6, 1998**
Applicant's Name: Bausch & Lomb Pharmaceuticals, Inc.
Product Name: Albuterol Sulfate Inhalation Solution,0.083%(base)

Labeling Deficiencies

1. UNIT DOSE CONTAINER (3 mL)

   Satisfactory at this time.

2. FOIL POUCH (28 x 3 mL and 60 x 3 mL)

   Satisfactory at this time.

3. CARTON (28 x 3 mL and 60 x 3 mL

   Delete the statements "AN to Ventolin Nebules®**" and "**Ventolin Nebules® is a registered trademark of Glaxo Wellcome Inc". Please note that these statements are intended for use when there are multiple-source reference listed drugs, which are not therapeutically equivalent.
   Upon approval, this application will have an AN rating to both Ventolin and Proventil. To label this product as you have proposed may render the product misbranded under section 502(a) of the Act. "AN to Ventolin Nebules®" could be misleading, in that, it implies that this product is not therapeutically equivalent to Proventil, and therefore could not be substituted.

4. INSERT - Satisfactory at this time.

Please revise your labeling, as instructed above, and submit 12 copies of final print.

Please note that further changes in your labeling, based upon changes in the approved labeling of the listed drug, may be required prior to approval.

Robert L. West, M.S., R.Ph.
Director

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? No
If no, list why: Draft labeling only.

Unit Dose Container Label:

Foil Pouch:

Unit Dose Carton Label:

Professional Package Insert Labeling:

Patient Package Insert Labeling:

Revisions needed post-approval:

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Ventolin®

NDA Number: 19-773

NDA Drug Name: Albuterol Sulfate Inhalation Solution 0.083%

NDA Firm: Glaxo-Wellcome

Date of Approval of NDA Insert and supplement #: October 30,1997
S-009

Has this been verified by the MIS system for the NDA?
Yes

Was this approval based upon an OGD labeling guidance? No

If yes, give date of labeling guidance:

Basis of Approval for the Container Labels: Approved Ventolin® container labeling.

Basis of Approval for the Carton Labeling: Approved Ventolin® carton labeling.

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book? Orange Book: Albuterol Sulfate Solution Inhalation Name used: Albuterol Sulfate Inhalation Solution	X		
If not USP, has the product name been proposed in the PF?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?	X		
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval): Do you have 12 Final Printed Labels and Labeling? Yes
Unit Dose Container Label: (3 mL) Satisfactory as of June 9, 1999 submission.
Foil Pouch: (28 x 3 mL and 60 x 3 mL) Satisfactory as of June 9, 1999 submission.
Unit Dose Carton Label: (28 x 3 mL and 60 x 3 mL)

Professional Package Insert Labeling:

Patient Package Insert Labeling: Satisfactory as of June 9, 1999 submission
Revisions needed post-approval:

BASIS OF APPROVAL:
Was this approval based upon a petition? No
What is the RLD on the 356(h) form: Ventolin®

NDA Number: 19-773/S-010
NDA Drug Name: Albuterol Sulfate Inhalation Solution 0.083%
NDA Firm: Glaxo-Wellcome

Date of Approval of NDA Insert and supplement #: Sept 18, 1998
Has this been verified by the MIS system for the NDA? Yes
Was this approval based upon an OGD labeling guidance? No

Basis of Approval for the Container Labels: Approved Ventolin® container labeling.
Basis of Approval for the Carton Labeling: Approved Ventolin® carton labeling.

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book? Orange Book: Albuterol Sulfate Solution Inhalation Name used: Albuterol Sulfate Inhalation Solution	X		
If not USP, has the product name been proposed in the PF?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			X
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			X
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?	X		
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	

Labeling (continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?			X
Does USP have labeling recommendations? If any, does ANDA meet them?			X
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	X		
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.			X
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T ½ and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.		X	

NOTES/QUESTIONS TO THE CHEMIST:

FOR THE RECORD:

1. Review based on the labeling of the reference listed drug (Ventolin®; NDA#19-773/S-010; Approved September 18, 1998; Revised May 1998).

2. Patent/ Exclusivities :

   There are no patents or exclusivities that pertain to this drug product.

3. Storage/ Dispensing Conditions :
   NDA: Store in refrigerator between 2°C and 8°C (36°F and 46°F). Protect from light. May be held at room temperature for up to 2 weeks before use. Discard if solution becomes discolored.
   ANDA: Same as NDA

4. Product Line :

   INNOVATOR: 3 mL each/prediluted/foil pouch of 25/25 count carton.
   APPLICANT:3 mL each/prediluted/foil pouch of 28 and 60/2 and 60 count carton.

5. The solution has been accurately described in the DESCRIPTION section. See page 961, Vol. 1.4. It is described as a clear, colorless solution.

6. Inactive Ingredients :

   The inactive ingredients as stated in the DESCRIPTION section appear to be correct. See page 84, Vol. 1.1.

7. All manufacturing is performed by Bausch & Lomb. Outside firms are utilized for testing only. See Page 198, Vol. 1.1.

8. Container/ Closure :

   The product will be packaged in a 3 mL fill size Resin in foil pouches and cartoned. See Page 897, Vol. 1.4.

6/17/99

Date of Review: ~~November 18, 1998~~
Date of Submission: ~~November 6, 1998~~ June 9, 1999

Reviewer: [signature] Date: 6/17/99

Team Leader: [signature] Date: 6/22/1999

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cc:

[illegible]RS&REV\75358NA3.L

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: ANDA 75358/000
Stamp: 15-APR-1998 Regulatory Due:
Applicant: BAUSCH AND LOMB
8500 HIDDEN RIVER PKY
TAMPA, FL 33637

Priority:
Action Goal:
Brand Name:
Established Name: ALBUTEROL SULFATE
Generic Name:
Dosage Form: SOL (SOLUTION)
Strength: 0.083%

Org Code: 600
District Goal: 15-JUN-1999

FDA Contacts: ID = 122344 , Project Manager
M. SMELA JR (HFD-625) 301-827-5848 , Team Leader

Overall Recommendation:

ACCEPTABLE on 24-MAY-1999 by S. FERGUSON (HFD-324) 301-827-0062

Establishment:
DMF No:
AADA No:

Profile: CTL
Last Milestone: OC RECOMMENDATION
Milestone Date: 13-MAY-1998
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

OAI Status: NONE

Responsibilities: FINISHED DOSAGE OTHER TESTER

Establishment: 1052807
BAUSCH AND LOMB PHARMACEUT
8500 HIDDEN RIVER PKY
TAMPA, FL 33637

DMF No:
AADA No:

Profile: LIQ
Last Milestone: OC RECOMMENDATION
Milestone Date: 24-MAY-1999
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

OAI Status: NONE

Responsibilities: FINISHED DOSAGE MANUFACTURER

Establishment:

DMF No:
NJ DI AADA No:

Profile: CTL
Last Milestone: OC RECOMMENDATION
Milestone Date: 13-MAY-1998
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

OAI Status: NONE

Responsibilities: FINISHED DOSAGE OTHER TESTER