CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

87-159

Generic Name: Fluocinolone Acetonide Topical Solution, 0.01%

Sponsor: National Pharmaceutical Manufacturing Company

Approval Date: June 16, 1982

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
87-159

CONTENTS

Reviews / Information Included in this ANDA Review.	
Approval Letter	X
Tentative Approval Letter	X
ANDAs	
Approvable Letter	
Final Printed Labeling	X
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology & Biopharmaceutics Reviews	
Bioequivalence Review(s)	
Administrative Document(s)	X
Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

87-159

APPROVAL LETTER

JUN 16 1982

NDA 87-159

National Pharmaceutical Manufacturing Company
A Division of Barre-National Inc.
Attention: Mr. Jim Allen
7205 Windsor Boulevard
Baltimore, Maryland 21207

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fluocinolone Acetonide Topical Solution, 0.01%.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate 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 Advertising and Labeling (HFD-170).

For Subsequent Campaigns: We call your attention to Regulation 21 CFR 310.300(b)(3) which requires that all material for any subsequent advertising or promotional campaigns at the time of their initial use be submitted to our Division of Drug Advertising and Labeling (HFD-170) with a completed Form FD-2253. A copy of Form FD-2253 is enclosed for your convenience.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

/S/ 6/16/82

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drugs
Bureaus of Drugs and Biologics

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements
Form FD 2253

cc: BLT-DO

HFD-616
HFD-534 (H. Zell)
HZell/LDavidson
R/D INITIAL HZell/MSeife
mstephens: 6/15/82(7951A)
Approval

/S/ 6/15/82

/S/ 6/15/82

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

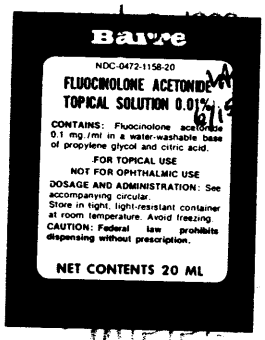
87-159

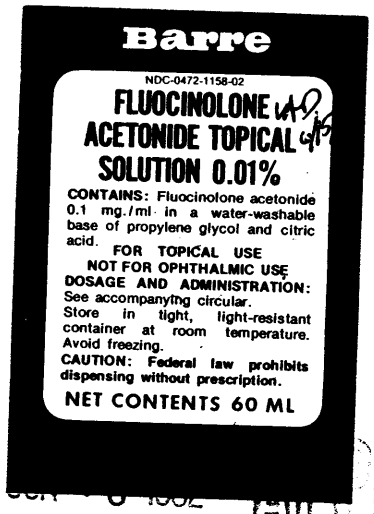
Final Printed Labeling

ORIGINAL

87-159 APR 26 1

L Davidson





APPROVED

APPROVED

APPROVED

FLUOCINOLONE ACETONIDE TOPICAL SOLUTION 0.01%

AD 6/15/82

DESCRIPTION: Fluocinolone acetonide has the chemical name 6α, 9α-difluoro-16α-hydroxyprednisolone-16, 17-acetonide. The solution contains fluocinolone acetonide 0.1mg./ml in a water-washable base of propylene glycol with citric acid.

ACTION: Topical steroids are primarily effective because of their anti-inflammatory, antipruritic and vasoconstrictive actions.

INDICATIONS: For relief of the inflammatory manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Topical steroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS: If irritation develops, the cream should be discontinued and appropriate therapy instituted.

In the presence of an infection, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid cream should be discontinued until the infection has been adequately controlled.

If extensive areas are treated or if occlusive technique is used, there will be increased systemic absorption of the corticosteroid and suitable precautions should be taken, particularly in children and infants.

Although topical steroids have not been reported to have an adverse effect on human pregnancy, the safety of their use in pregnant women has not absolutely been established. In laboratory animals, increases in incidences of fetal abnormalities have been associated with exposure of gestating females to topical corticosteroids, in some cases at rather low dosage levels. Therefore, drugs of this class should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time. Product is not for ophthalmic use.

JUN 16 1982

APPRO

ADVERSE REACTIONS: The following local adverse reactions have been reported with topical corticosteroids: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

DOSAGE AND ADMINISTRATION:

OPEN THERAPY

Apply three or four times daily as follows: A sparing amount, sufficient to cover the affected area, should be spread evenly over the surface and rubbed in gently until it disappears. In hairy sites, the hair should be parted to allow direct contact with the lesion.

OCCLUSIVE DRESSING TECHNIQUE

Apply directly to the affected area, leaving a visible thin coat on the surface. Cover completely with a pliable non-porous film. Changes of dressing may be done once or twice daily as determined on an individual basis by the physician.

Some plastic films may be flammable and due care should be exercised in their use. Similarly, caution should be employed when such films are used on children or left in their proximity, to avoid the possibility of accidental suffocation.

CAUTION: Federal law prohibits dispensing without prescription.

HOW SUPPLIED: 20 ml and 60 ml plastic squeeze bottles.

FORM NO. 1158
10/79

Mfg. by National Pharmaceutical Mfg. Co.
Baltimore, Maryland 21207

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

87-159

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW NDA 87-159

3. NAME AND ADDRESS OF APPLICANT
National Pharmaceutical Manufacturing Co.
Baltimore, Maryland 21207

4. AE NUMBER
DESI 8653
F.R. 4/2/71

5. SUPPLEMENT(s)
Original (9/26/79)

6. NAME OF DRUG
Fluocinolone Acetonide

8. SUPPLEMENT(s) PROVIDE(s) FOR:
Original submission (amended)

9. AMENDMENTS AND OTHER DATES:
3/19/82 Amendment dated 3/15/82 - Container specs.
4/26/82 Amendment dated 4/20/82 - FPL.
6/7/82 Correspondence dated 6/3/82 - Stability Data

10. PHARMACOLOGICAL CATEGORY
Adrenocortical Steriod

11. HOW DISPENSED
RX

12. RELATED IND/NDA/DMF(s)
NDA 12-787 Synalar Solution 0.01%
DMF

13. DOSAGE FORM(s)
Topical Solution

14. POTENCY
0.01%

15. CHEMICAL NAME AND STRUCTURE
$C_{24}H_{30}F_2O_6$

17. COMMENTS
Remaining deficiencies have been answered sufficiently for approval.

18. CONCLUSIONS AND RECOMMENDATIONS
Approval letter should issue.

19. REVIEWER: /S/ DATE COMPLETED: June 15, 1982

/S/ 6/15/82

Redacted 2

pages of trade secret and/or confidential commercial information

CHEMIST'S REVIEW NDA 87-159

3. NAME AND ADDRESS OF APPLICANT
National Pharmaceutical Manufacturing Co.
Baltimore, MD 21207

4. AF NUMBER
DESI 8653
F.R. 4/2/71

5. SUPPLEMENT(s)
Original (9/26/79)

6. NAME OF DRUG
Fluocinolone Acetonide

8. SUPPLEMENT(s) PROVIDE(s) FOR:
Original submission (amended)

9. AMENDMENTS AND OTHER DATES:
8/19/81 See Attachment

10. PHARMACOLOGICAL CATEGORY
Adrenocortical Steroid

11. HOW DISPENSED
RX

12. RELATED IND/NDA/DMF(s)
Synalar Solution 0.01% - NDA 12-787

13. DOSAGE FORM(s)
Topical Solution

14. POTENCY
0.01%

15. CHEMICAL NAME AND STRUCTURE
$C_{24}H_{30}F_2O_6$

17. COMMENTS
Deficiencies remaining:

[redacted]

18. CONCLUSIONS AND RECOMMENDATIONS
BIO deferred. Reviewed waiting firm letter should issue detailing the remaining deficiencies as noted in review Section 17 above.

Enclosure: Class Labeling Guideline

19. REVIEWER: /S/ Yoczell 3/1/82 DATE COMPLETED: 2/26/82

Addenda to Chemist's Review

Insert 9 - Correspondence History

10/5/79	Original ANDA submission dated 9/26/79
12/14/79	Correspondence dated 12/12/79 - results of [redacted]
6/20/80	Amendment dated 6/18/80 - location change
9/19/80	Amendment dated 9/10/80 - location change
8/24/81	Amendment dated 8/19/81 - reply to 4/21/81 letter

FDA

10/15/79	Acknowledgement of ANDA submission
10/23/79	Inspection request [redacted]
10/24/79	Medical review [redacted] - Labels require revision
4/20/81	Rev w/f [redacted] Review
4/21/81	Letter sent - Rev w/f - request stability container specs, labeling revision, updated specifications
2/22/82	2nd Inspection request - new location

Redacted 2

pages of trade secret and/or confidential commercial information

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

87-159

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 87-159

DATE APPROVAL LETTER ISSUED: JUN 16 1982

TO: Press Relations Staff (HFI-40)

FROM:
- [X] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [X] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [X] HUMAN
- [ ] VETERINA

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG
Fluocinolone Acetonide

DOSAGE FORM
Topical Solution 0.01%

HOW DISPENSED
- [X] RX
- [ ] OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s). If amount is declared on label.)

0.1 mg/ml Fluocinolone Acetonide, USP

NAME OF APPLICANT (Include City and State)

National Pharmaceutical Manufacturing Company
Division of Barre-National, Inc.
7205 Windsor Boulevard
Baltimore, Maryland 21207

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

Adrenocortical Steroid

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: Lynn A. Davidson /S/ DATE: June 15, 1982

FORM APPROVED BY

NAME: Howard C. Zell, Ph.D. /S/ DATE: 6/15/82

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date MAR 3 1982

From Manufacturing Review Branch, HFD-322
Division of Drug Manufacturing

Subject APPROVABLE ANDA 87-159 FLUOCINOLONE ACETONIDE TOPICAL SOLN

To Director
Division of GENERIC DRUG MONOGRAPHS (HFD 534)
Drug Products
Attn: LYNN DAVIDSON

APPLICANT: NATIONAL PHARM MFG CO, BALTIMORE, MD

MANUFACTURING:

NATIONAL PHARMACEUTICAL MFG CO, BALTIMORE, MD EI 10/80

TESTING LAB:

We have evaluated the operations of THE ABOVE as they relate to compliance with Current Good Manufacturing Practice Regulations (21 CFR 211) with the exception of expiration dating (211.137) and stability testing (211.166) for the referenced application(s). Since you evaluate the applicants' submission of stability data and proposed expiration date, you should make the determination that the stability testing is adequate to support the proposed expiration date. If you desire, you can include appropriate references to (211.137) and (211.166) as deviations directly into your non-approvable letter if you conclude the stability testing is inadequate. Otherwise, we conclude there is no reason to withhold approval of the subject application(s) insofar as CGMP compliance of this/these firm(s) is concerned for the type of operations as specified in this/these pending application(s).

Our evaluation is based in part on Establishment Inspection and Quality Assurance Profile information.

/S/
Seymour Fishman

WSF
3/3/82

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Division of Drug Manufacturing, HFD-320 DATE: February 22, 1982

FROM : Division of Generic Drug Monographs, HFD- 534

Requester's Name: Lynn Davidson Phone: 443-1390

SUBJECT: GMP EVALUATION REQUEST

NDA,ANDA, and SUPPLEMENT NUMBER: 87-159

DRUG Trade Name: Fluocinolone Acetonide Topical Solution

DRUG Non-Proprietary Name: —

DRUG CLASSIFICATION: ___ A or B ___ 1C X Other

PRODUCT CODE: LIQ (description of dosage form, e.g., compressed tablet;coated tablet; soft gelatin capsule;liquid;See Table)

180 DAY DATE: 5/14/82

APPLICANT'S NAME: National Pharmaceutical Manufacturing Company

ADDRESS: 7205 Windsor Boulevard, Baltimore, MD 21207

FACILITIES TO BE EVALUATED: (Name, Address, and Responsibility)

(1) Applicant (Manufacturer)

(2)

(3)

FOR HFD-320 USE ONLY

Date Received: _____ Date Completed: _____

cc: HFD-320 (Orig)
HFD- (2 Copies)

REVIEW OF ANDA

DATE COMPLETED: 10-24-79

ANDA #: 87-159

CO. NAME: National Pharm. Mfg. Co.
Baltimore, MD 21215

F.R. DATE: 4-28-71; 6-1-73; 2-11-75

NAME OF DRUG: Fluocinolone Acetonide Topical Solution, 0.01%

DATE OF SUBMISSION: (date of receipt) 10-5-79

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Bioavailability requirement is deferred for this drug.

2. Review of Labeling:

Container label: draft copies for 20 ml. and 60 ml. containers ---

-- add "For topical use only"
-- add "Not for ophthalmic use"
-- Provide for lot or control number and an expiration date. / see application p. 1 of 4 JMK

Package insert: (draft copy) -- satisfactory.

CONCLUSION:
1. The draft copies of the container labels need revision as noted above.
2. The draft copy of the package insert is satisfactory. Have firm send in FPL identical in content.

RECOMMENDATIONS: The company is to be so notified.

/S/
J.R. Carr, D.D.S.

cc:dup
JRC/wlh/10-30-79

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION

2. NDA NUMBER
87-159

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
National Pharmaceutical MFG. Co.
A Division of Barre -National Inc.
Baltimore,MD

4. AF NUMBER

5. SUPPLEMENT (S)
NUMBER(S) | DATE(S)

6. NAME OF DRUG
Flucinolone Acetonide

7. NONPROPRIETARY NAME

8. SUPPLEMENT(S) PROVIDES FOR:
NEW APPLICATION, submission of an amendment indicating a new manufacturing facility at 7205 Windsor Blvd. Baltimore,MD. 21207, and additional information

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES
6/18/80
9/10/80
12/12/80

10. PHARMACOLOGICAL CATEGORY
topical corticosteroid

11. HOW DISPENSED
☒ RX ☐ OTC

12. RELATED IND/NDA/DMF(S)
Synalar Sol-0.01%
Syntex Labs. Inc.

13. DOSAGE FORM (S)
topical solution

14. POTENCY *(ies)*
0.01%

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT ☐ YES ☐ NO
REVIEWED ☐ YES ☐ NO

17. COMMENTS

APPEARS THIS WAY
ON ORIGINAL

18. CONCLUSIONS AND RECOMMENDATIONS
rev w/f

19.
NAME J.M.Ross
REVIEWER /S/
DATE COMPLETED

DISTRIBUTION ☐ ORIGINAL JACKET ☐ REVIEWER ☐ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

CHEMIST'S REVIEW, Page 2

Enter evaluation or comments for each item. If necessary, continue on 8" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER 87-159

20. COMPONENTS AND COMPOSITION *(6, 7)*

see application

21. FACILITIES AND PERSONNEL *(8a,b)*

22. SYNTHESIS *(8c)*

[redacted] St.

23. RAW MATERIAL CONTROLS *(8d,e)*

a. NEW DRUG SUBSTANCE

active ingredient is tested as per USP XIX

REQUESTED: update tests and specifications as per USP XX

b. OTHER INGREDIENTS

excipients are tested as per USP

REQUESTED: Update tests and specifications as per USP XX

24. OTHER FIRM(S) *(8i)*

25. MANUFACTURING AND PROCESSING *(8g,h,j,k)*

26. CONTAINER *(8l)*

white plastic bottles

27. PACKAGING AND LABELING *(8l,m)*

28. LABORATORY CONTROLS *(In-Process and Finished Dosage Form) (8n)*

finished dosage form is tested as per USP

REQUESTED: update the tests and specificaions as per USP XX

29. STABILITY *(8p)*

long term stability protocl submitted and challenge study protocl submitted

NO DATA submitted

30. CONTROL NUMBERS *(8c)*

31. SAMPLES AND RESULTS *(9)*

a. VALIDATION

b. MARKET PACKAGE

32. LABELING *(4)*

Container labels: revise/ m.o. report

Package inserts: Satisfactory

33. ESTABLISHMENT INSPECTION

34. RECALLS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

87-159

CORRESPONDENCE

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.

7205 Windsor Blvd. / Baltimore, Md. 21207 / phone (301) 298-1000

Orig

June 3, 1982

ORIG NEW CORRES

Bureau of Drugs, HFD-530
Division of Generic Drug Monographs
ATTN: Document Control Room #16-70
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen,

Reference is made to our abbreviated new drug application #87-159 for Fluocinolone Acetonide Topical Solution 0.01%.

Stability data in support of our twenty-four month expiration dating is enclosed. This includes both challenge data and long term room temperature data.

We believe we have now met all the requirements of your division. Please expedite the approval.

If you have any additional questions, please call.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.

Redacted 1

pages of trade secret and/or confidential commercial information

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.
7205 Windsor Blvd. / Baltimore, Md. 21207 U.S.A. phone (301) 298-1000

Drug

4/28/82
Firm has been made aware of Class Labeling Guideline in our letter of 3/24/82 M.S.

Certified Mail #4425579

April 20, 1982

Bureau of Drugs, HFD-530
Division of Generic Drug Monographs
ATTN: Document Control Room #16-70
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

EPL

Gentlemen,

Reference is made to our abbreviated new drug application #87-159 for Fluocinolone Acetonide Topical Solution 0.01%.

Please find enclosed twelve final printed copies of the container label and package insert as submitted in draft form with our amendment dated August 19, 1981.

If you have any questions, please call.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.
Certified Mail #4425516

7205 Windsor Blvd. / Baltimore, Md. 21207 U.S.A. phone (301) 298-1000

March 15, 1982

RESUBMISSION

NDA ORIG AMENDMENT

Bureau of Drugs, HFD-530
Division of Generic Drug Monographs
ATTN: Document Control Room #16-70
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen,

Reference is made to our abbreviated new drug application #87-159 for Fluocinolone Acetonide Topical Solution 0.01% and your letter dated March 2, 1982.

1. The stability data is underway to substantiate the proposed 24 month expiration date. Three month challenge data at 40°C and 50°C will be available in several weeks. It will be submitted upon completion.

2. [redacted]

3. Twelve copies of the final printed labeling for the package inserts and container labels as submitted in draft form will be sent after being printed.

If you have any questions, please call.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.

RECEIVED
MAR 19 1982
GENERIC DRUGS

MAR 2 1982

ANDA 87-159

National Pharmaceutical Mfg. Company
A Division of Barre National Inc.
Attention: Mr. Jim Allen
7205 Windsor Boulevard
Baltimore, Maryland 21207

Gentlemen:

Reference is made to your abbreviated new drug application submitted September 26, 1979 pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fluocinolone Acetonide Topical Solution, 0.01%.

Reference is also made to your amendment dated August 19, 1981.

We refer also to our letter of April 24, 1981.

We have reviewed this abbreviated new drug application - and other material submitted to the application as listed above - and request the following aforementioned information:

1. Stability data is required to substantiate the proposed 24 month expiration date. Challenge data from studies at 37-40°C and 75% RH can be used to set a tentative expiration date until the results from long-term stability studies at controlled room temperature are available. We have not yet received any stability data.

2. By addition to your application, or by a letter of authority to reference the pertinent Drug Master File, the characteristics and testing of containers and closures for suitability for intended use is required.

3. Please submit twelve (12) copies of your final printed labeling for package inserts and container labels as submitted in draft form with your amendment dated August 19, 1981. (Enclosed are the class labeling guidelines which will take effect December 1, 1982 as per the Federal Register notice of October 6, 1981).

Please let us have your response promptly.

Sincerely yours,

/S/ 2/26/82
/S/ 3/1/82
/S/ mje 3/2/82

Martin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc: BLT-DO
HFD-616
HFD-534 (H.Zell
HZell/LDavidsor
R/D INITIAL HZell/MSeife
mstephens: 2/25/82(7431A)
Rev w/f

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.
7205 Windsor Blvd. / Baltimore, Md. 21207 / phone (301) 298-1000

Certified Mail #2452791

9/2/81
Draft labeling of immediate container label is satisfactory.
Request 7 pg
M.B.

August 19, 1981

RESUBMISSION

NDA ORIG AMENDMENT

DRAFT LABELING

Bureau of Drugs, HFD-530
Division of Generic Drug Monographs
ATTN: Document Control Room #16-70
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen,

Reference is made to our abbreviated new drug application #87-159 for Fluocinolone Acetonide Topical Solution 0.01% and your letter dated April 24, 1981.

1. Draft copies of Container Labels with statement, "For Topical Use Only - Not for Ophthalmic Use", is found in Enclosure 1. Zip code has been corrected. Printed Labels and Inserts will be submitted at a later date.

2. Three properly dated FD Form 356H are found in Enclosure 2.

3a. [redacted]

b. [redacted]

c. [redacted]

4. [redacted]

We appreciate your response to this letter.

Sincerely,
NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.

APR 24 1981

NDA 87-159

National Pharmaceutical Mfg. Company
A Division of Barre National Inc.
Attention: Mr. Jim Allen
7205 Winsor Blvd.
Baltimore, MD 21207

Gentlemen:

Reference is made to your undated abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fluocinolone Acetonide Topical Solution, 0.01%.

We acknowledge receipt of your communications dated December 12, 1979, June 18, 1980, and September 10, 1980, indicating a change in the address of the manufacturing facility, and additional control information.

We have completed the review of this abbreviated new drug application. However, before we can reach a final conclusion the following information is necessary:

1. Labeling

a) Container Labels: Add the following statements-
"For topical use only"
"Not for ophthalmic use"

Submit twelve final printed revised labels, with zip code corrected.

b) Package Inserts: Submit twelve final printed inserts, identical content to the draft copies.

2. Submit a properly dated FD Form 356H. Three copies are enclosed for your convenience.

3. Assurance that the drug dosage form and components will comply with the specifications and tests described in an official compendium, if such article is recognized therein, or if not listed, or if the article differs from the compendium drug, that the specifications and tests applied to the drug and its components are adequate to assure their identity, strength, quality and purity. In this regard:

b) Submit the actual data obtained from performing the required tests and specifications on the finished dosage form.

c) In regard to your container/closure system, indicate the type of white plastic bottles used and describe the dropper plug, white closure. (Reference: If bottles are used, it is recommended that the tests and specifications indicated in the U.S.P. XX p. 953 be followed).

4. In regard to stability studies:

Expand the stability studies with such data in the reporting format describing such characteristics as-

Please submit the above information promptly.

Sincerely yours,

/S/ 4/24/81

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Enclosure: Three copies of FD Form 356H

cc:
BALT-DO
HFD-616
JRCarr/JLMeyer/JMRoss
R/D init JLMeyer/MSeife/4/17/81
pb/4/20/81
rev w/f
2116E

/S/ 4/21/81

/S/
4/21/81

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.

Drug

7205 Windsor Blvd. / Baltimore, Md. 21207 / phone (301) 298-1000

Certified Mail #2054865

September 10, 1980

Bureau of Drugs, HFD-530
Division of Generic Drug Monographs
ATTN: Document Control Room #16-70
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen,

This letter is in reference to the following unapproved ANDA's:

1-	[redacted]	ANDA# [redacted]	
2-	[redacted]	ANDA#	
3-	[redacted]	ANDA# [redacted]	
4-	[redacted]	ANDA# [redacted]	
5-	[redacted]	ANDA# [redacted]	
6-	[redacted]	ANDA#	
7-	Chlorpromazine Syrup 100mg/ml	ANDA#86-863	
8-	[redacted]	ANDA#	
9-	[redacted]	ANDA# [redacted]	
10-	[redacted]	ANDA# [redacted]	
11-	[redacted]	ANDA# [redacted]	
12-	[redacted]	ANDA# [redacted]	
13-	Hydrocortisone 1% Acetic Acid Nonaqueous 2% Otic Solution	ANDA#87-143	
14-	Acetic Acid-Nonaqueous 2% Otic Solution	ANDA#87-146	
15-	[redacted]	ANDA# [redacted]	
16-	[redacted]	ANDA# [redacted]	
17-	Fluocinolone Acetonide Topical Solution 0.01%	ANDA#87-159	
18-	Triamcinolone Acetonide Lotion 0.025%	ANDA#87-191	
19-	[redacted]	ANDA# [redacted]	
20-	[redacted]	ANDA# [redacted]	
21-	Gamma Benzene Hexachloride 1% Shampoo (Lindane)	ANDA#87-266	
22-	Lindane (Gamma Benzene Hexachloride Lotion 1%)	ANDA#87-313	
23-	[redacted]	ANDA# [redacted]	
24-	[redacted]	ANDA# [redacted]	

Reference is made to our supplements dated June 18, 1980 which provided for a manufacturing facilities change. Please find enclosed a more extensive description of the new facilities. We have also enclosed a more detailed layout of the building and have also provided an expanded view of the Quality Control Laboratory. Additionally, the first three manufactured lots and at least one new lot manufactured each year will be placed in the stability testing program.

We expect to have the new facility inspected for compliance with current Good Manufacturing Practices by the Division of Drug Manufacturing within the next few weeks.

If you have any further questions please contact us.

Sincerely,
NATIONAL PHARMACEUTICAL MFG. CO.
Jim Allen
Jim Allen
Senior Chemist

JA/ck
Enc.

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.
4128 Hayward Avenue / Baltimore, Md. 21215 / phone (301) 542-5272

Oreg

Certified Mail #2052667

June 18, 1980

Bureau of Drugs, HFD-530
Division of Generic Drug Monographs
ATTN: Document Control Room #16-70
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen,

This letter is in reference to the following pending, unapproved ANDA's:

1-	[redacted]	ANDA #[redacted]
2-	[redacted]	ANDA #[redacted]
3-	[redacted]	ANDA #[redacted]
4-	[redacted]	ANDA [redacted]
5-	[redacted]	ANDA #[redacted]
6-	[redacted]	ANDA [redacted]
7-	Chlorpromazine Syrup 100 mg./ml.	ANDA #86-863
8-	[redacted]	ANDA #[redacted]
9-	[redacted]	ANDA [redacted]
10-	[redacted]	ANDA #[redacted]
11	[redacted]	ANDA #[redacted]
12-	[redacted]	ANDA #[redacted]
13-	Hydrocortisone 1% Acetic Acid Nonaqueous 2% Otic Solution	ANDA #87-143
14-	Acetic Acid-Nonaqueous 2% Otic Solution	ANDA #87-146
15-	[redacted]	ANDA #[redacted]
16-	[redacted]	ANDA [redacted]
17-	Fluocinolone Acetonide Topical Solution 0.01%	ANDA #87-159
18-	Triamcinolone Acetonide Lotion 0.025%	ANDA #87-191
19-	[redacted]	ANDA [redacted]
20	[redacted]	ANDA #[redacted]
21-	Gamma Benzene Hexachloride 1% Shampoo (Lindane)	ANDA #87-266
22-	Lindane (Gamma Benzene Hexachloride Lotion 1%)	ANDA #87-313
23-	[redacted]	ANDA #[redacted]
24-	[redacted]	ANDA #[redacted]

Our operating facilities will be moved from the present site at 4128 Hayward Avenue, Baltimore, Md. 21215 to our new plant at 7205 Windsor Boulevard, Baltimore, Md. 21207.

This transfer will be performed in stages.

We guarantee that there will be no changes in the formulations, manufacturing procedures, specifications and tests for any of these products.

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.

4128 Hayward Avenue / Baltimore, Md. 21215 / phone (301) 542-5272

We will place the first two batches of these products manufactured in the new facility on stability and samples will be tested at 3, 6, 12, 18, 24 and 36 months and the data obtained from these tests will be submitted to FDA.

We would like approval of the new facilities for the manufacturing, control and marketing of these products.

Since the move will begin very shortly, we would most appreciate your giving our request priority.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.

APPEARS THIS WAY
ON ORIGINAL

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.
Certified Mail #2051530

4128 Hayward Avenue / Baltimore, Md. 21215 / phone (301) 542-5272

Drug

December 12, 1979

Bureau of Drugs, HFD-530
ATTN: Document Control Room #16-72
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Gentlemen,

Reference is made to our ANDA #87-159 for Fluocinolone Acetonide Topical Lotion 0.01%.

Please find enclosed the results of the USP preservative challenge test on the above product.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.

Redacted 2

pages of trade secret and/or confidential commercial information

OCT 15 1979

NDA 87-159

National Pharmaceutical Manufacturing Company
A division of Barre-National Inc.
Attention: James Mendelsohn
4128 Hayward Avenue
Baltimore, MD 21215

Gentlemen:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NAME OF DRUG: Fluocinolone Acetonide Topical Solution 0.01%

DATE OF APPLICATION: Undated

DATE OF COVER LETTER: September 26, 1979

DATE OF RECEIPT: October 5, 1979

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the NDA number shown above.

Sincerely yours,

/S/ 10/15/79

/Martin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

BALT-DO Dup HFD-614
JLMeyer/mlb/10-12-79
ack

10/12/79

NATIONAL
PHARMACEUTICAL MFG. CO.
A DIVISION OF BARRE-NATIONAL INC.

Certified Mail #615606

ABBREVIATED NEW DRUG APPLICATION
87-159

4128 Havward Avenue / Baltimore, Md. 21215 / phone (301) 542-5272

September 26, 1979

Bureau of Drugs (HFD-106)
ATTN: Document Control Room #8B-21
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Enclosed ANDA for Fluocinolone Acetonide Topical Solution (0.01%)

Gentlemen,

Information included as follows:

(1) Stability studies on the submitted formula are in progress and results will be submitted periodically.

(2) Draft copies of labels and inserts.

(3) Three signed NDA forms FD356H.

(4) Please note General Information section following the NDA application. This will answer many frequently asked questions.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

James Mendelsohn
Vice President

JM/ck
Enc.