CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

40-417

Generic Name: Hydrocortisone Lotion USP, 2.5%

Sponsor: Vintage Pharmaceuticals, Inc.

Approval Date: July 30, 2003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

CONTENTS

Reviews / Information Included in this ANDA Review.

Approval Letter(s)	X
Tentative Approval Letter(s)	
Final Printed Labeling	X
CSO Labeling Review(s)	X
Medical Officer Review(s)	
Chemistry Review(s)	X
Microbiology Review(s)	
Bioequivalence Review(s)	X
Administrative Document(s)	X
Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

APPROVAL LETTER

ANDA 40-417

JUL 30 2003

Vintage Pharmaceuticals, Inc.
Attention: Christopher J. Nascone
120 Vintage Drive
Huntsville, AL 35811

Dear Sir:

This is in reference to your abbreviated new drug application dated June 27, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Hydrocortisone Lotion USP, 2.5%.

Reference is also made to your amendment dated May 13, 2003.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Hydrocortisone Lotion USP, 2.5% to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Hytone® Lotion, 2.5%, of Dermik Laboratories, Inc.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy, which you intend to use in your initial 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 Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

/s/ for

7/30/2003

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

FINAL PRINTED LABELING

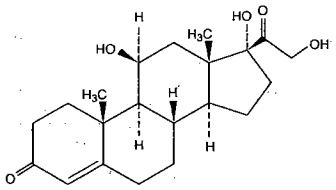
HYDROCORTISONE
LOTION, USP 2.5%

Rx only

DESCRIPTION

Each mL of Hydrocortisone Lotion 2.5% contains 25 mg of hydrocortisone in a vehicle consisting of carbomer 940, cetyl alcohol, cholesterol, isopropyl myristate, polysorbate 40, propylene glycol, propylene glycol monostearate, purified water, simethicone, sorbic acid, sorbitan palmitate, trolamine.

Chemically, hydrocortisone is [Pregn-4-ene-3,20-dione, 11, 17, 21-trihydroxy-, (11ß)-] with the molecular formula ($C_{21}H_{30}O_5$) and is represented by the following structural formula:



JUL 30 2003

APPROVED

Its molecular weight is 362.47 and its CAS Registry Number is 50-23-7. The topical corticosteroids, including hydrocortisone, constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic, and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.

(See **DOSAGE AND ADMINISTRATION.**)

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

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

PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS: Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

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

Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions, especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests

The following tests may be helpful in evaluating the HPA axis suppression:

Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy
Teratogenic Effects: Pregnancy Category C
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities *not* likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION
Topical corticosteroids are generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition. Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED
In bottles of 2 FL OZ.

Keep out of the reach of children.

Manufactured by:
VINTAGE PHARMACEUTICALS, INC.
Huntsville, AL 35811

65678
Rev 10/02
R1

NDC 0254-9209-50

HYDROCORTISONE

LOTION, USP

2.5%

SHAKE WELL BEFORE USING

Rx only

2 FL OZ (60 mL)

DOSAGE AND ADMINISTRATION:
For complete product information see package insert.

For external use only.
Avoid contact with eyes.
Keep out of the reach of children.

Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
HUNTSVILLE, AL 35811

Rev. 10/02 R1
65882 7785

NDC 0254-9209-50

HYDROCORTISONE

LOTION, USP

2.5%

SHAKE WELL BEFORE USING

Rx only

2 FL OZ (60 mL)

APPROVED
JUL 30 2003

INDICATIONS AND USAGE:
See package insert.

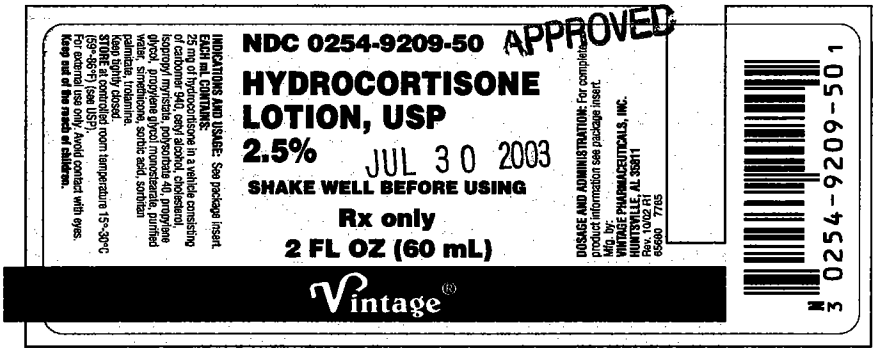
EACH mL CONTAINS:
25 mg of hydrocortisone in a vehicle consisting of carbomer 940, cetyl alcohol, cholesterol, isopropyl myristate, polysorbate 40, propylene glycol, propylene glycol monostearate, purified water, simethicone, sorbic acid, sorbitan palmitate, trolamine.

Keep tightly closed.
STORE at controlled room temperature 15°-30°C (59°-86°F) (see USP).

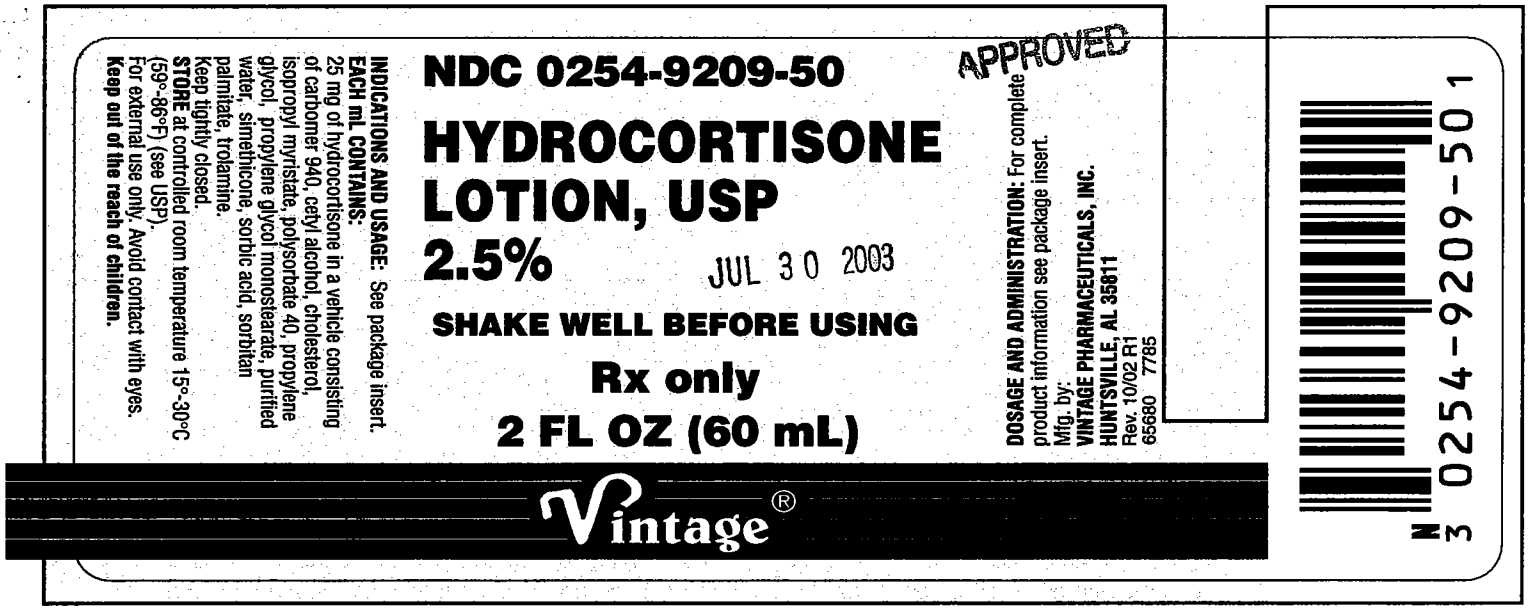
Vintage®

N 3 0254-9209-50 1

Margo



LABEL SIZE 1 5/8 X 4 1/4 INCHES



ENLARGED FOR PROOFING

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

CSO LABELING REVIEW(S)

Kathy 1-1

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

ANDA Number: 40-417 Date of Submission: June 27, 2000

Applicant's Name: Vintage Pharmaceutical Inc.

Established Name: Hydrocortisone Lotion USP, 2.5%

Labeling Deficiencies:

1. CONTAINER (60 mL)

   The information on the label lacks the conspicuousness required by Section 502(c) of the Act. The green print against the shaded background is difficult to read. In order to assure that computer generated labels meet this requirement, they must be of true size, color, and clarity. Refer to 21 CFR 201.15(a)(6) for guidance.

2. CARTON (60 mL) – Satisfactory

3. INSERT - Satisfactory

Please revise your labels, as instructed above, and submit in final print.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes –

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

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.

Wm. Peter Rickman
Acting 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? Yes No If no, list why:
Container Labels: (60 mL)
Carton Labeling: (60 mL) – Satisfactory as of June 27, 2000 submission
Professional Package Insert Labeling: Satisfactory as of June 27, 2000 submission
Patient Package Insert Labeling: Satisfactory as of June 27, 2000 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: Hytone Lotion 2.5%
ANDA Number: 80-473
ANDA Drug Name: Hydrocortisone Lotion USP, 2.5%
ANDA Firm: Dermik Laboratories, Inc.
Date of Approval of NDA Insert and supplement #:
Has this been verified by the MIS system for the NDA? Yes No
Was this approval based upon an OGD labeling guidance? No
Basis of Approval for the Container Labels: Side-by-side comparison
Basis of Approval for the Carton Labeling: Side-by-side comparison

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?		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.			
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	
Because of proposed packaging configuration or for any other reason, does this applicant meet fail to meet all of the unprotected conditions of use of referenced by the RLD?		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.			
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.			

NOTES/QUESTIONS TO THE CHEMIST: None

FOR THE RECORD:

1. **Labeling review based on the labeling for the reference listed drug, (Hytone Lotion 2.5% - Laboratories, Inc.(ANDA 80-473); revised 12/96).**

2. **Packaging**
   The RLD packages its lotion in 2 fl oz (59 mL) bottles.

   The applicant is proposing to package its product in white, ' — 2 fl oz (60 mL) bottles with flip top caps.

3. **Labeling**
   Vintage has been asked to enhance the readability of the container labels.

4. **Inactive Ingredients**
   There does not appear to be a discrepancy between the inactives listed in the labeling and the C&C Statements.

5. **USP Issues**
   USP – Preserve in tight containers
   RLD – Store at room temperature. Keep tightly closed.
   ANDA – Store at CRT 15 - 30°C (59-86°F). Keep tightly closed.

6. **Bioequivalence Issues – Waiver granted September 1, 2000**

7. **Patent/Exclusivity Issues – None pending**

Date of Review: **Date of Submission:**

January 30, 2001 **June 27, 2000**

Primary Reviewer: **Date:**

1/30/01

Team Leader: **Date:**

1/31/2001

cc: ANDA: 40-417
DUP/DIVISION FILE
HFD-613/LGolson/JGrace (no cc)
\\CDS008\WP51F99\FIRMSNZ\VINTAGE\LTRS&REV\40417na1.l
Review

APPROVAL SUMMARY

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

ANDA Number: 40-417

Date of Submission: March 19, 2002 and November 4, 2002

Applicant's Name: Vintage Pharmaceutical Inc.

Established Name: Hydrocortisone Lotion USP, 2.5%

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

- Do you have 12 Final Printed Labels and Labeling? Yes
- Container Labels: (60 ml) – Satistifactory in FPL as of November 4, 2002, submission [Vol. 2.1, revised 10/02; code # 65680]
- Carton Labeling: (1 x 60 mL) – Satisfactory in FPL as of November 4, 2002, submission. [Vol. 2.1, revised 10/02; code #65682]
- Professional Package Insert Labeling: Satisfactory in FPL as of November 4, 2002, submission. [Vol. 2.1 revised 10/02; code #65678]

BASIS OF APPROVAL:

- Was this approval based upon a petition? No
- What is the RLD on the 356(h) form: Hytone Lotion 2.5%
- NDA Number: 80-473
- NDA Drug Name: Hydrocortisone Lotion USP, 2.5%
- NDA Firm: Dermik Laboratories, Inc.
- Date of Approval of NDA Insert: November 14, 1997
- 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: Side-by-side comparison
- Revisions needed post-approval: No
- Patents/Exclusivities: Refer to chart below.

Patent Data – NDA 80-473

Patent No.	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
			There are no unexpired patents for this product in the Orange Book Database.		NONE

Exclusivity-Data – NDA 80-473

Code	Reference	Expiration	Labeling Impact
	There is no unexpired exclusivity for this product.		NONE

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?		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	

FOR THE RECORD:

1. **MODELING LABEL**
   Labeling review based on the labeling for Hytone lotion, 2.5% (NDA 80-473) by Dermik Laboratories, Inc.; approved November 14, 1997; revised 12/96 - PDR).

2. **INACTIVE INGREDIENTS**
   There is no discrepancies between the listing of inactives in the product labeling and in the C&C statements.
   Vol. A1.1 pg. 60]

3. **STORAGE TEMPERATURE RECOMMENDATIONS COMPARSON**
   - USP - Preserve in tights containers.
   - RLD – Store at CRT 15°-30°C (59°-86°F).
   - ANDA – Same as RLD

4. **PACKAGING CONFIGURATION**
   - RLD - packages its lotion in 2 floz (60 ml) bottles
   - ANDA – packages its lotion into white ——. 2 fl oz (60 ml) bottles with flip top caps.

5. **FINISHED DOSAGE FORM**
   - RLD: Lotion
   - ANDA: White to off white Lotion

   [Vol. A1.1 pg. 284]

6. **MANUFACTURING FACILITY OF FINISHED DOSAGE FORM**

   Vintage Pharmaceuticals, Inc.
   120 Vintage Drive
   Huntsville, AL 35811
   [Vol. A1.1 pg. 127]

Date of Review: 11/12/02 **Date of Submission:** March 19, 2002 and November 4, 2002

B. Weitzman

Primary Reviewer: Beverly Weitzman **Date:** 11/13/02

Team Leader: John D Grace **Date:** 11/14/2002

---

cc:

ANDA: 40-471
DUP/DIVISION FILE
HFD-613/JGrace (no cc)
V:\FIRMSAM\Vintage\LTRS&REV\40417ap.l

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 40-417

3. NAME AND ADDRESS OF APPLICANT

Vintage Pharmaceuticals Inc.
120 Vintage Drive
Huntsville, AL 35811

4. LEGAL BASIS FOR SUBMISSION

The listed drug is Hytone Lotion. The applicant is not aware of any patent or exclusivity for the product.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydrocortisone Lotion, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission June 27, 2000

10. PHARMACOLOGICAL CATEGORY

Glucocorticoid, anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF#

[redacted]

13. DOSAGE FORM

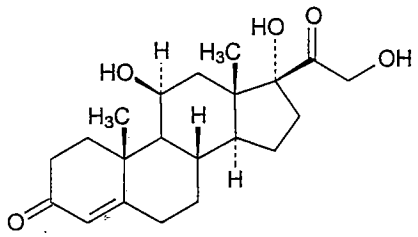
Lotion

14. POTENCY

2.5%

15. CHEMICAL NAME AND STRUCTURE

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β)-..



16. RECORDS AND REPORTS

None

17. COMMENTS

The application is deficient.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is not approvable.

19. REVIEWER: DATE COMPLETED:

Kathy P. Woodland January 31, 2001

Redacted 13

Page(s) of trade secret and /or confidential commercial information

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 40-417

3. NAME AND ADDRESS OF APPLICANT

Vintage Pharmaceuticals Inc.
120 Vintage Drive
Huntsville, AL 35811

4. LEGAL BASIS FOR SUBMISSION

The listed drug is Hytone Lotion. The applicant is not aware of any patent or exclusivity for the product.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydrocortisone Lotion, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission	June 27, 2000
Amendment	March 19, 2002

10. PHARMACOLOGICAL CATEGORY

Glucocorticoid, anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF#

[ ]

[ ]

13. DOSAGE FORM

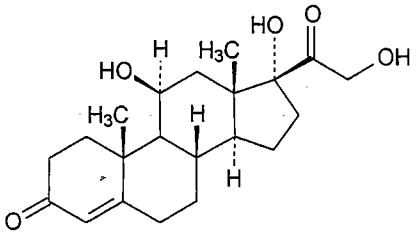
Lotion

14. POTENCY

2.5%

15. CHEMICAL NAME AND STRUCTURE

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β)-..



16. RECORDS AND REPORTS

None

17. COMMENTS

The application is deficient in the areas of synthesis, raw material controls, laboratory controls, and stability.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is not approvable.

19. REVIEWER: DATE COMPLETED:

Kathy P. Woodland June 14, 2002

Redacted 11

Page(s) of trade secret and /or confidential commercial information

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 40-417

3. NAME AND ADDRESS OF APPLICANT

Vintage Pharmaceuticals Inc.
120 Vintage Drive
Huntsville, AL 35811

4. LEGAL BASIS FOR SUBMISSION

The listed drug is Hytone Lotion. The applicant is not aware of any patent or exclusivity for the product.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydrocortisone Lotion, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission	June 27, 2000
Amendment	March 19, 2002
Amendment	November 4, 2002
Amendment	November 8, 2002

10. PHARMACOLOGICAL CATEGORY

Glucocorticoid, anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF#

[

[

]

]

13. DOSAGE FORM

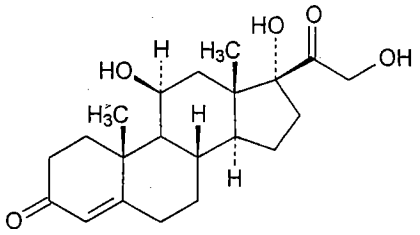
Lotion

14. POTENCY

2.5%

15. CHEMICAL NAME AND STRUCTURE

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β)-..



16. RECORDS AND REPORTS

None

17. COMMENTS

The application is deficient in the area of raw material controls, and environmental assessment.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is not approvable (MINOR amendment).

19. REVIEWER: Kathy P. Woodland

DATE COMPLETED: December 16, 2002
Revised December 31, 2002
Revised January 10, 2003

Redacted 11

Page(s) of trade secret and /or confidential commercial information

1. CHEMISTRY REVIEW NO. 4

2. ANDA # 40-417

3. NAME AND ADDRESS OF APPLICANT

Vintage Pharmaceuticals, Inc.
120 Vintage Drive
Huntsville, AL 35811

4. LEGAL BASIS FOR SUBMISSION

The listed drug is Hytone Lotion. The applicant is not aware of any patent or exclusivity for the product.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydrocortisone Lotion, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission	June 27, 2000
Amendment	March 19, 2002
Amendment	November 4, 2002
Amendment	November 8, 2002
Amendment	***May 13, 2003***

10. PHARMACOLOGICAL CATEGORY

Glucocorticoid, anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF#

[

]

[

]

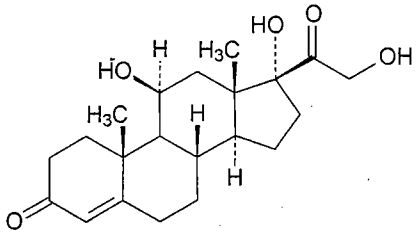
13. DOSAGE FORM

14. POTENCY

Lotion 2.5%

15. CHEMICAL NAME AND STRUCTURE

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β)-..



16. RECORDS AND REPORTS

None

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER: DATE COMPLETED:

Kathy P. Woodland June 26, 2003

Redacted 6

Page(s) of trade secret and /or confidential commercial information

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

BIOEQUIVALENCE REVIEW(S)

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 40-417 APPLICANT: Vintage Pharmaceuticals

DRUG PRODUCT: Hydrocortisone Lotion USP, 2.5%

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

for Barbara M Davit

Dale P. Conner, Pharm. D.
Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

E MAIL
DATE 9-6-2000
1:14 pm EDT
S.G.NERURKAR
HFD 655 MPN2 130

We in DBE have decided to notify our colleagues in Chemistry, whenever there is an overage of an active ingredient. The details are as follow:

ANDA	DRUG	FIRM	REVIEWER	SUBM. DATE
40-417	HYDROCOR-TISONE LOTION	VINTAGE	GJP SINGH	6-27-00

Thanks.
Vijay

APPEARS THIS WAY
ON ORIGINAL

CC: ANDA #40-417
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-655/ Reviewer
HFD-655/ Bio team Leader

V:\FIRMSNZ\VINTAGE\LTRS&REV\40417W.600.doc

Endorsements: (Final with Dates)
HFD-655/ Reviewer GOPS 8/25/00 8/25/00
HFD-655/ Bio team Leader
for HFD-650/ D. Conner BDD 9/1/00

BIOEQUIVALENCY - ACCEPTABLE submission date: 6/27/2000

1. **WAIVER** (WAI) Strengths: 2.5%
✓ Outcome: AC

WINBIO COMMENTS: The test product is eligible for a waiver of in vivo bioequivalence study requirements.

APPEARS THIS WAY
ON ORIGINAL

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA #: 40-417 SPONSOR: Vintage Pharmaceuticals

DRUG AND DOSAGE FORM: Hydrocortisone Lotion

STRENGTH(S): 2.5%

TYPES OF STUDIES : N/A

CLINICAL STUDY SITE (S): N/A

STUDY SUMMARY : N/A.
DISSOLUTION : N/A.
WAIVER: The test product is eligible for a waiver of in vivo bioequivalence study requirements.

DSI INSPECTION STATUS

Inspection needed: **NO**	Inspection status:	Inspection results:
First Generic: **No** New facility __No___ For cause __No___ Other _None__		

PRIMARY REVIEWER: (Gur J.P. Singh, Ph.D.) BRANCH: II

INITIAL: Gurjaipal Singh DATE: 8/25/00

TEAM LEADER: (Shriniwas Nerurkar, Ph.D.) BRANCH: II

INITIAL: S D Nerurkar DATE: 8/25/2000

for DIRECTOR, DIVISION OF BIOEQUIVALENCE : Dale P. Conner, Pharm. D.

INITIAL: DPC DATE: 9/1/00

Hydrocortisone
Lotion, 2.5%
ANDA #40-417
Reviewer: Gur J. P. Singh
40417W.600

Vintage Pharmaceuticals
Huntsville, AL 35811
Submission Date:
June 27, 2000

Review of a Waiver Request

The firm has submitted a request for waiver of in vivo bioequivalence study requirements for its hydrocortisone lotion, 2.5%. The reference listed drug that is the basis for this submission is Hytone® lotion 2.5% (NDA #80-473), manufactured by Dermik Laboratories. It is indicated for the relief of the inflammatory and puritic manifestations of corticosteroid-responsive dermatoses.

Formulation Comparison: (Not to be released under FOI)

Ingredients	Test [Mg/mL (%)]	Reference [Mg/mL (%)]
Hydrocortisone	[redacted]	25.0 (2.5)
Propylene Glycol USP		potency not given
Sorbic Acid NF		potency not given
Carbomer 940 NF		potency not given
Polysorbate 40 NF		potency not given
		potency not given
Isopropyl Myristate NF		potency not given
Cetyl Alcohol NF		potency not given
Cholesterol		potency not given
Sorbitan Palmitate		potency not given
Simethicone USP		potency not given
Propylene Glycol Stearate		potency not given
Purified Water		potency not given

APPEARS THIS WAY
ON ORIGINAL

Comments

1. Hydrocortisone Lotion is a pre-1962 drug product with an AT-rating in the Orange Book. The Division of Bioequivalence (DBE) has previously granted waivers for two generic formulations (ANDAs 40-247 and 40-351)

2. The test product uses the same active ingredient as present in the innovator product, Hytone[R] Lotion, 2.5%. The test product uses — overage of the active ingredient. However, the amount of active ingredient present in the test products is within the USP specifications of 90-110%.

3. The test product contains the same inactive ingredients. The amount of each ingredient is within the acceptable limit based on *the Inactive Ingredient Guide (1996)*, the two hydrocortisone lotions previously approved by DBE, and the reviewer's communication with the Division of Drug Information Resources.

4. The request for the waiver of in vivo bioequivalence study requirements for Vintage Pharmaceuticals' hydrocortisone lotion, 2.5%, may be granted pursuant to 21 CFR Section 320.22 (C).

Recommendation

The Division of Bioequivalence agrees that the information submitted by Vintage Pharmaceuticals demonstrates that its Hydrocortisone Lotion USP, 2.5%, falls under 21 CFR Section 320.22 (C) of the Bioavailability/ Bioequivalence Regulations. The waiver of in vivo bioequivalence study requirements for Hydrocortisone Lotion, 2.5% is granted. Vintage Pharmaceuticals' Hydrocortisone Lotion USP, 2.5%, is therefore deemed to be bioequivalent to Dermik's Hytone® Lotion, 2.5%.

Gur J.P. Singh, Ph.D. 8/25/00
Division of Bioequivalence,
Review Branch II

RD INITIALED SNERURKAR
FT INITIALED SNERURKAR: 8/25/2000

CONCUR: DATE: 9/1/00

for Dale P. Conner, Pharm. D.
Director,
Division of Bioequivalence

V:\FIRMSNZ\VINTAGE\LTRS&REV\40417W.600.doc

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

ADMINISTRATIVE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date MAY 1 2001

From Consumer Safety Officer, Investigations & Pre-approval Compliance Branch/DMPQ (HFD-324)

Subject Concurrence with District Approval Recommendation, ANDA 75993, ANDA ——, ANDA 40417, ANDA 40391

To Patricia Beers- Block - Branch Chief, Review Support Branch
Office of Generics Drugs

Applicant/ Manufacturer: Vintage Pharmaceuticals, Inc
Huntsville, Alabama

The Division of Manufacturing and Product Quality (DMPQ) has completed a review of the Establishment Inspection Report (EIR) for the inspection conducted at the referenced manufacturing facility from January 22, 2001 through February 02, 2001. Based on this review, we concur with the district's recommendation to approve the subject ANDA's.

The inspection did uncover issues that may be of significance to the chemistry review and involving ANDA's: —— 40417, 40391 and 75993.

We have enclosed a copy of the EIR for your information. If you have questions, feel free to contact me at (301) 827-0062.

Wilma Labrador
Compliance Officer

Enclosure:
cc:

HFR-SE400	C. Draper	Dist. Director
HFD-324	W. Labrador	
HFD-324	R/F	

Concur: BHartman

RECORD OF TELEPHONE CONVERSATION

DATE:	September 30, 2002
ANDA:	40-417
DRUG PRODUCT:	Hydrocortisone Lotion USP, 2.5%
FDA:	Shing H. Liu, Ph.D. S. H. Liu 9/30/02
FIRM:	Vintage Pharmaceuticals, Inc.
CONVERSATION WITH:	Christopher Nascone Regulatory Affairs
PHONE NUMBER:	256-859-2222
TOPIC:	NF tests for Propylene Glycol Monostearate

Reference is made to the firm's request for clarification (dated 09/27/02) regarding Item #A.3 in the most recent NA letter. Mr. Nascone had called Ms. Wanda Pamphile (project manager) on 09/25/02 on the subject of this T-con.

The most recent NA letter asked the firm to revise the Propylene Glycol Monostearate raw material specification to include all current NF tests. The firm stated again in the 09/27/02 letter that they were unable to locate a source of this material that meets all NF specifications. Dr. Liu informed the firm that the Agency understood the firm's problem. Since this is a current problem for the industry, the language used in the NA letter was carefully chosen. We did not ask the firm to revise the Propylene Glycol Monostearate raw material specification to include all current NF specifications. Instead, we asked the firm to revise the Propylene Glycol Monostearate raw material specification to include all current NF tests. The test results, which might not meet the current NF specifications, would be acceptable.

Mr. Christopher Nascone thanked Dr. Liu for the response.

ANDA: 40-417
Telecon Binder

\\CDS013\OGDS11\FIRMSNZ\VINTAGE\TELECONS\40417.093002.TC.doc

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-417

CORRESPONDENCE

Vintage
Pharmaceuticals, LLC

120 Vintage Drive
Huntsville, AL 35811

Phone (256) 859-2222
Fax (256) 858-0025

May 13, 2003

Mr. Gary Buehler, Director
Office of Generic Drugs, CDER, FDA
Document Control Room, Rm. 150
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT
N/Am

RE: ANDA # 40-417
Hydrocortisone Lotion, USP 2.5%
25 mg per mL
Minor Amendment

In accordance with Section 505(j) of the FD&C Act, as amended, and 21 CFR Part 314.94, we are submitting a minor amendment to the ANDA for the above product in response to a minor amendment letter dated January 13, 2003. The following item is included immediately following the NDA form 356h:

- Field Copy Certification

The archival copy of the amendment consists of one volume. The review copy consists of one red-jacketed chemistry & manufacturing volume and one separately bound, orange-jacketed bioequivalence volume.

We look forward to your early response. If you have any questions or comments regarding this amendment, please contact the undersigned, or as an alternate, Mr. John Schultz, Plant Manager, at Tel. (256) 859-2222.

Sincerely,
VINTAGE PHARMACEUTICALS, INC.

CJ Nascone

Christopher J. Nascone
Regulatory Affairs

RECEIVED
MAY 15 2003
OGD / CDER

5/15/03

Vintage
Pharmaceuticals, LLC

120 Vintage Drive
Huntsville, AL 35811

Phone (256) 859-2222
Fax (256) 858-0025

November 8, 2002

Mr. Gary Buehler, Director
Office of Generic Drugs, CDER, FDA
Document Control Room, Rm. 150
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT
AJ / RP

RE: ANDA # 40-417
Hydrocortisone Lotion, USP 2.5%
25 mg per mL
Amendment

Dear Mr. Buehler:

In accordance with Section 505(j) of the FD&C Act, as amended, and 21 CFR Part 314.94, we are submitting an amendment to our Abbreviated New Drug Application for the above product.

This amendment is being submitted to provide additional information regarding the status of the Drug Master File (# ——— of the ——————————— Vintage just received this letter from the ——— stating that their DMF file had been updated.

The archival copy of the amendment consists of one volume. The review copy consists of one red-jacketed chemistry & manufacturing volume and one separately bound, orange-jacketed bioequivalence volume.

If you have any questions or comments regarding this submission, please contact the undersigned, or as an alternate, Mr. John Schultz, Plant Manager, at Tel. (256) 859-2222.

Sincerely,
VINTAGE PHARMACEUTICALS, INC.

CJ Nascone

Christopher J. Nascone
Regulatory Affairs

RECEIVED
NOV 1 2 2002
OGD / CDER

Vintage
Pharmaceuticals, LLC

120 Vintage Drive
Huntsville, AL 35811

Phone (256) 859-2222
Fax (256) 858-0025

November 4, 2002

Mr. Gary Buehler, Director
Office of Generic Drugs, CDER, FDA
Document Control Room, Rm. 150
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT
N|am

FPL

RE: ANDA # 40-417
Hydrocortisone Lotion, USP 2.5%
25 mg per mL
Minor Amendment

Dear Mr. Buehler:

In accordance with Section 505(j) of the FD&C Act, as amended, and 21 CFR Part 314.94, we are submitting an amendment to our Abbreviated New Drug Application for the above product.

This amendment is in response to a Minor Amendment letter dated September 6, 2002. This amendment also includes revised final printed labeling.

The archival copy of the amendment consists of one volume. The review copy consists of one red-jacketed chemistry & manufacturing volume and one separately bound, orange-jacketed bioequivalence volume.

We look forward to your early response. If you have any questions or comments regarding this submission, please contact the undersigned, or as an alternate, Mr. John Schultz, Plant Manager, at Tel. (256) 859-2222.

Sincerely,
VINTAGE PHARMACEUTICALS, INC.

C J Nascone

Christopher J. Nascone
Regulatory Affairs

RECEIVED
NOV 0 5 2002
OGD / CDER

20-1-11

120 Vintage Drive
Huntsville, AL 35811

Vintage
Pharmaceuticals, Inc.

Phone (256) 859-2222
Fax (256) 858-0025

March 19, 2002

Mr. Gary Buehler, Acting Director
Office of Generic Drugs, CDER, FDA
Document Control Room, Rm. 150
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT
N/AC

RE: ANDA # 40-417
Hydrocortisone Lotion, USP 2.5%
25 mg per mL
Major Amendment

Dear Mr. Buehler:

In accordance with Section 505(j) of the FD&C Act, as amended, and 21 CFR Part 314.94, we are submitting an amendment to our Abbreviated New Drug Application for the above product.

This amendment is in response to a Major Amendment letter dated March 9, 2001.

As requested in section B of the letter, Vintage acknowledges that all firms referenced in the application must be in compliance with cGMP at the time of approval. Vintage further acknowledges that the USP method is the regulatory method and will prevail in the event of a dispute.

This amendment also includes final printed container labeling.

The archival copy of the amendment consists of one volume. The review copy consists of one red-jacketed chemistry & manufacturing volume and one separately bound, orange-jacketed bioequivalence volume.

We look forward to your early response. If you have any questions or comments regarding this submission, please contact the undersigned, or as an alternate, Mr. John Schultz, Plant Manager, at Tel. (256) 859-2222.

Sincerely,
VINTAGE PHARMACEUTICALS, INC.

C J Nascone

Christopher J. Nascone
Regulatory Affairs

RECEIVED
MAR 21 2002
OGD / CDER

ANDA 40-417

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

MAR 18 2002

Vintage Pharmaceuticals, Inc.
Attention: Christopher J. Nascone
3241 Woodpark Blvd.
Charlotte, NC 28206

Dear Sir:

This letter is in reference to your Abbreviated New Drug Application (ANDA) dated June 27, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Hydrocortisone Lotion USP, 2.5%.

We refer you to our "Not Approvable" letter dated March 9, 2001, which detailed the deficiencies identified during our review of your ANDA. The Agency may consider an ANDA applicant's failure to respond to a "Not Approvable" letter within 180 days to be a request by the applicant to withdraw the ANDA under 314.120(b). Your amendment to the application is overdue. You must amend your application within 10 days of receipt of this letter. Otherwise, an action to withdraw the application will be initiated per 21 CFR 314.99.

If you do not wish to pursue approval of this application at this time, you should request withdrawal in accord with 21 CFR 314.65. A decision to withdraw the application would be without prejudice to refiling.

If you have further questions you may contact Saundra T. Middleton, Project Manager, Regulatory Support Branch, at (301) 827-5862.

APPEARS THIS WA
ON ORIGINAL

Please send all correspondence to the following address:

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Sincerely yours,

Samuha J. Middleton

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA # 40-417
DUP/Division File
HFD-610/PRickman

Endorsement:
HFD-617/GDavis, Chief, RSB, S. Middleton for date 3/18/02
HFD-617/SMiddleton, CSO, S. Middleton date 3/18/02
Word File
V:\FIRMSNZ\VINTAGE\LTRS&REV\40417.OTH
F/T by EEH 03/14/02
10 DAY LETTER!

APPEARS THIS WAY
ON ORIGINAL

ANDA 40-417

Vintage Pharmaceuticals Inc.
Attention: Christopher J. Nascone AUG 14 2000
120 Vintage Drive
Huntsville, AL 35811

Dear Sir:

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

NAME OF DRUG: Hydrocortisone Lotion USP, 2.5%

DATE OF APPLICATION: June 27, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: June 28, 2000

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 ANDA number shown above.

Should you have questions concerning this application, contact:

Elaine Hu
Project Manager
(301) 827-5848

Sincerely yours,

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research