

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
40374

CORRESPONDENCE

ANDA 40-374 .

Thames Pharmacal Co., Inc.
Attention: Srinivasa Rao
2100 Fifth Avenue
Ronkonkoma, NY 11779
|||||

JUL 16 1999

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.

Reference is also made to the telephone conversation dated July 1, 1999 and your correspondence dated July 6, 1999.

NAME OF DRUG: Triamcinolone Acetonide Ointment USP, 0.025%

DATE OF APPLICATION: June 1, 1999

DATE (RECEIVED) ACCEPTABLE FOR FILING: June 7, 1999

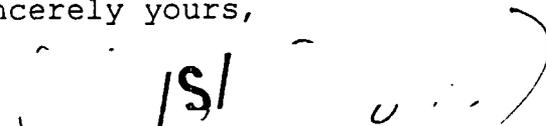
We will correspond with you further after we have had the opportunity to review the application.

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

Should you have questions concerning this application, contact:

Joseph Buccine
Project Manager
(301) 827-5848

Sincerely yours,


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

01111111111111111111
(800) 225-1003

2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (516) 737-1155

BY FAX
Fax # (301) 594 1174

July 20, 1999

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855 2773
Attn: Mr. Nasser MahmudRe: Supporting Documents for Triamcinolone Acetonide
Ointment USP, 0.025% ANDA # 40-374

Dear Sir,

In reference to our recent telephonic conversation dated July 20, 1999
enclosed please find the following:

- (i) Detailed information on the contract laboratories used for
assaying this product.

I assume that the above information is satisfactory and request to
review our application.

Any questions you could reach me at 516 737 1155

Sincerely yours,
Thames Pharmaceutical Co., Inc.

A handwritten signature in black ink, appearing to read "S. Rao", followed by the date "7/20/99".

Srinivasa Rao M.Pharm. M.S., R.Ph., F.A.S.P.W.
Supervisor, Research and Development



2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (516) 737-1155

March 9, 2001

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

ORIG AMENDMENT
N/FA FPL



Ref: FAX AMENDMENT - ANDA # 40-374
Triamcinolone Acetonide Ointment USP, 0.025%

Dear Ms. Hu:

Pursuant to your fax amendment dated December 21, 2000, Thames Pharmacal Co., Inc. has the following as its response.

A. Deficiencies:

- Please be informed that you cannot rely on the certificate of analysis provided by the drug substance manufacturer until you validated the manufacturer. Please revise your specifications for the drug substance to include test and specifications for residual solvents and organic volatile impurities.**

Response

We have validated our manufacturers of the drug substance by performing organic volatile impurities and residual solvents as per USP 24 Supplement II (test procedure <467> Method I).

Three batches of Triamcinolone Acetonide, USP of each manufacturer were tested by an outside contract laboratory () and all lots tested conformed to the specification.

Since we have validated the drug substance manufacturer and, moreover, this OVI testing is not included in the monograph for the drug substance Triamcinolone Acetonide, USP, we, at the present time, will rely on the certificate of analysis provided by the drug substance manufacturer (page# 3-15).

2. **Please tighten your limits for individual and total degradants for the finished drug product.**

Response

We have tightened our individual and total degradants for the finished drug product to % and % respectively (page# 16).

- B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:**

1. **Please provide a categorical exclusion request under 21 CFR 25.31 (a) and certify that you are in compliance with all applicable local, state and federal environmental regulations.**

Response

Please see attached certification (page# 17).

Labeling Deficiencies:

Please submit your labels and labeling in final print.

Response

Please see attached labels and labeling (page# 18-67).

Very truly yours,

Thames Pharmacal Co., Inc.

By: 
Srinivasa Rao, M. Pharm, M.S., R.Ph.
Director, Regulatory Affairs



2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (516) 737-1155

April 12, 2001

NC

NEW C

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

Ref: TELEPHONE AMENDMENT - ANDA # 40-374
Triamcinolone Acetonide Ointment USP, 0.025%

Dear Ms. Hu:

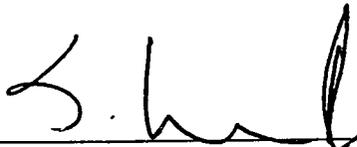
Pursuant to our conversation dated April 11, 2001, Thames Pharmacal has the following as its response:

- A. Since [redacted] is no longer in business, we are unable to use their services. Henceforth, we are withdrawing [redacted] as our contract laboratory from our application.
- B. The New Jersey division of [redacted]

If you have any questions, please feel free to contact me at (631) 737-1155.

Very truly yours,

Thames Pharmacal Co., Inc.

By: 
Srinivasa Rao, M. Pharm, M.S., R.Ph.
Director, Regulatory Affairs



OUTSIDE NEW YORK
(800) 225-1003



2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (631) 737-1155 FAX (631) 737-3185

NC
NEW CORRESP

June 1, 2001

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Attention: Ms. Pat Block

Re: Telephone Amendment – ANDA #40-374
Triamcinolone Acetonide Ointment USP, 0.025%

By fax: 301-594-0183

Dear Ms. Block:

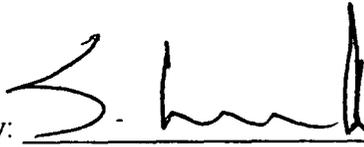
Pursuant to our conversation dated May 30, 2001, Thames Pharmacal Co., Inc. has the following as its response:

Tests on residual solvents including Acetone (NMT ppm), Methanol (NMT ppm) and Dimethylformamide (NMT ppm) will be performed on three batches of the drug substance Triamcinolone Acetonide, USP and the results will be reported in our annual report for this drug product.

If you have any questions, please call me at (631) 737-1155.

Very truly yours,

Thames Pharmacal Co., Inc.

By: 
Srinivasa Rao, M. Pharm, M.S., R.Ph.
Director, Regulatory Affairs





2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (631) 737-1155 FAX (631) 737-3185

May 31, 2001

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Attention: Ms. Pat Block

ORIG. AMENDMENT FA

Re: Telephone Amendment – ANDA #40-374
Triamcinolone Acetonide Ointment USP, 0.025%

Dear Ms. Block:

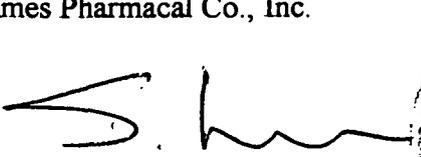
Pursuant to our conversation dated May 30, 2001, Thames Pharmacal Co., Inc. has the following as its response:

Tests on residual solvents including Acetone (NMT ppm), Methanol (NMT ppm) and Dimethylformamide (NMT ppm) will be performed on three batches of the drug substance Triamcinolone Acetonide, USP and the results will be reported in our annual report for this drug product.

If you have any questions, please call me at (631) 737-1155.

Very truly yours,

Thames Pharmacal Co., Inc.

By: 
Srinivasa Rao, M. Pharm, M.S., R.Ph.
Director, Regulatory Affairs





OUTSIDE NEW YORK
(800) 225-1003

2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (516) 737-1155

May 8, 2001

ANDA ORIG AMENDMENT
N/FA

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

Re: Telephone Amendment - ANDA # 40-374
Triamcinolone Acetonide Ointment USP, 0.025%

Dear Ms. Block:

Pursuant to our conversation dated May 8, 2001, Thames Pharmacal has the following as its response:

- 1. We are withdrawing as our contract testing
laboratory.

If you have any questions, please call me at (631) 737-1155.

Very truly yours,

Thames Pharmacal Co., Inc.

By: S. Rao
Srinivasa Rao, M. Pharm, M.S., R.Ph.
Director of Regulatory Affairs





2100 FIFTH AVENUE, RONKONKOMA, NY 11779 (516) 737-1155

July 6, 1999

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park north II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Attn: **Mr. Nazir Mahmood**

Re: Supporting Documents for Triamcinolone Acetonide
Ointment USP, 0.025% ANDA # 40-374

Dear Sir:

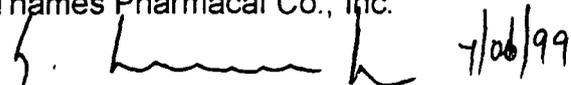
In reference to our recent telephonic discussion dated July 1, 1999 enclosed please find the following:

- (i) Letter stating the basis of our submission (pg. no 3).
- (ii) A patent certification statement (pg. no 4).
- (iii) Comparison between proposed drug and reference listed drug (pg. no 5).
- (iv) A side by side comparison of container, carton and insert labeling between reference listed drug and proposed drug (pg. no 6-11).

I assume that the above information is satisfactory and request to review our application.

Any questions you could reach me at 516 737 1155.

Sincerely yours,
Thames Pharmacal Co., Inc.

 7/06/99
Srinivasa Rao, M.Pharm., MS, R.Ph., FASCP
Supervisor, Research and Development

