CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76067

CORRESPONDENCE

ANDA 76-067

FEB – 1 2002

Clay-Park Labs, Inc.
Attention: Candis Edwards
1700 Bathgate Avenue
Bronx, NY 10457

Dear Madam:

This is in reference to your abbreviated new drug application dated December 21, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Mometasone Furoate Ointment USP, 0.1%.

Reference is also made to your amendments dated November 28, December 14, and December 27, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Elocon Ointment of Schering Corp., is currently subject to a period of patent protection (U.S. Patent No. 4,472,393 - the '393 patent). Your application contains a Paragraph III Certification to the patent under Section 505(j)(2) (A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of the '393 patent. As noted in the agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange Book", this patent was to have expired on September 18, 2001. However, this period was extended under Section 111 of the Food and Drug Administration Modernization Act (21 U.S.C.

355a (1997) for an additional 6 months with the granting of pediatric exclusivity to Schering. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '393 patent has expired, i.e., currently March 18, 2002.

In order to reactivate your application prior to final approval, please submit an amendment within 30 days. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. In the event no changes were made, an amendment should be submitted documenting that fact. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to March 18, 2002, you should amend your application accordingly.

At the time you submit any amendments, you should contact Sarah Ho, R.Ph., Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

/S/

Gary Buehler 2/1/02
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 76-067

JAN 24 2001

Clay-Park Labs, Inc.
Attention: Candis Edwards
1700 Bathgate Avenue
Bronx, NY 10457

Dear Madam:

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: Mometasone Furoate Ointment USP, 0.1%

DATE OF APPLICATION: December 21, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: December 26, 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:

Michelle Dillahunt
Project Manager
(301) 827-5848

Sincerely yours,

/S/ for

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

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

February 7, 2002

Ms. Sarah Ho, Project Manager
Food and Drug Administration
Office of Generic Drugs, CDER
Metro Park North II
7500 Standish Place
Rockville, MD 20855

OTC AMENDMENT
N/AM.

SUBMITTED BY FAX

MINOR AMENDMENT -

FINAL APPROVAL REQUESTED

RE: ANDA # 76-067 Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Ho:

In response to the Tentative Approval Letter for Mometasone Furoate Ointment USP, 0.1%, ANDA #76-067, dated February 1, 2002 (**See Attachment 1**), Clay-Park Labs, Inc. hereby submits a Minor Amendment in order to reactivate our application for Mometasone Furoate Ointment USP, 0.1% prior to final approval of this product.

Clay-Park Labs, Inc. (CPL) acknowledges that we cannot market our product, Mometasone Furoate Ointment USP, 0.1% before March 18, 2002 due to the pediatric exclusivity and that we need a final approval letter from the agency.

CPL hereby states that there are no changes in the conditions under which Mometasone Furoate Ointment USP, 0.1% was tentatively approved February 1, 2002, including labeling, chemistry, manufacturing and controls information.

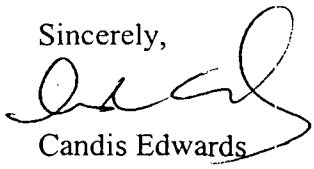
As requested by the Office of Generic Drugs, CPL has submitted the required information designated as a minor amendment, which is assigned a 30 to 60 days review period. In order to assure that CPL receives final product approval prior to March 18, 2002, which is less than 60 days from now, we respectfully request an expedited review of this amendment so that we can be in a position to market the product on March 18, 2002.

CENTER FOR DRUG EVALUATION AND RESEARCH
FEB - 8 2002
OGD

Your attention to this matter is appreciated. Should you have any comments or require any further clarifications on this amendment, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,



Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

December 14, 2001

Ms. Sarah Ho, Project Manager
Food and Drug Administration
Office of Generic Drugs, CDER
Metro Park North II
7500 Standish Place
Rockville, MD 20855

TA
DRUG AMENDMENT

Submitted by FAX – Hard Copy to Follow

TELEPHONE AMENDMENT

RE: ANDA # 76-067 Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Ho:

In response to the teleconference between FDA and Clay-Park Labs, Inc. on December 13, 2001, in reference to the Fax Amendment dated November 29, 2001 on ANDA # 76-067 for Mometasone Furoate Ointment USP, 0.1%, Clay-Park Labs, Inc. has revised the specifications for related substances in Mometasone Furoate Ointment USP, 0.1% based on the Agency's recommendations as follows:

Stability Evaluation	Old Specification	New Specification
Unknown Individual	NMT %	NMT %
Total	NMT %	NMT %

The revised stability monograph for Mometasone Furoate Ointment USP, 0.1% is included in **Attachment 1**.

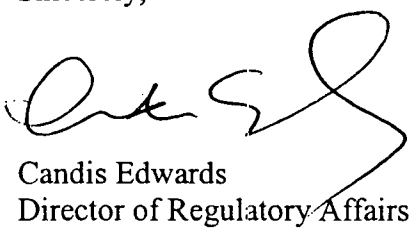
Additionally, the post-approval stability protocols for the 15 g and 45 g tubes, previously submitted on August 21, 2001 in the Minor Amendment on pages 091 – 104, have been revised to incorporate the revision of the specifications for the related substances in Mometasone Furoate Ointment USP, 0.1%. **See Attachment 2** for the revised Post-Approval Stability Protocols.

We anticipate that the revisions submitted herein satisfy all of the Agency's requirements regarding CMC issues for Clay-Park Labs, Inc.'s pending ANDA # 76-067 for Mometasone Furoate Ointment USP, 0.1%

Should you have any comments or require any further clarifications on this amendment, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,



Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

November 28, 2001

ORIG AMENDMENT
N/FA

Ms. Sarah Ho, Project Manager
Food and Drug Administration
Office of Generic Drugs, CDER
Metro Park North II
7500 Standish Place
Rockville, MD 20855

FAX AMENDMENT

RE: ANDA # 76-067 Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Ho:

In reference to the deficiency letter dated November 20, 2001 **(Attachment 1)** on our abbreviated new drug application for Mometasone Furoate Ointment USP, 0.1%, ANDA # 76-067, and pursuant to 21 CFR 314.96 (a) (1), Clay-Park Labs, Inc. hereby submits the deficiency response for Chemistry section, designated as a FAX Amendment.

Should you have any comments or require any further clarifications on this amendment, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,

Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

September 6, 2001

NEW CORRESP

NC
Acknowledge
NA!
9/14/01.

Michelle Dillahunt, Project Manager
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

INFORMATIONAL AMENDMENT

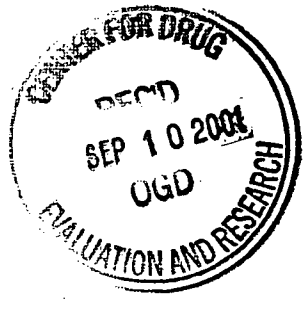
Re: ANDA # 76-067 Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Dillahunt:

Pursuant 21 CFR 314.60 (a), Clay-Park Labs, Inc. hereby submits an Informational Amendment to ANDA # 76-067 for Mometasone Furoate Ointment USP, 0.1%, to update the ANDA file, regarding our retest policy for inactive ingredients.

As described on page 1734 (Attachment 1) in Section VIII (3) of the original ANDA, Clay-Park Labs, Inc., previously had a three (3) year retest policy for inactive ingredients. We received comments regarding the retest policy on pending ANDA applications from various chemists, requesting a change in the retest policy for inactive ingredients.

We conferred with the District Office, and have revised the retest policy for inactive ingredients from three (3) years to one (1) year to meet the current Industry standards.



Should you have any comments or require any further clarification on this amendment, please contact the undersigned as follows:

Telephone (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,

Candis Edwards
Director of Regulatory Affairs

Enclosure: Attachment 1
cc: Joseph Famulare
Director, Division of Manufacturing and Product Quality – HFD 320

Richard Trainor
Compliance Officer, FDA District Office

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

August 31, 2001

ORIG AMENDMENT
NC

Michelle Dillahunt, Project Manager
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

INFORMATIONAL AMENDMENT

RE: ANDA 76-067 Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Dillahunt:

Clay-Park Labs, Inc. hereby submits an Informational Amendment to update ANDA # 76-067 for Mometasone Furoate Ointment USP, 0.1% to include USP 24 <661>, Physiochemical Testing – Plastics for the 45 g Tubes (**Attachment 1**).

Please note that we also neglected to point out the fact that the viscosity testing requirement was deleted in the bulk monograph that was submitted on the Minor Amendment dated August 21, 2001. The viscosity testing of the bulk is not required because the product is transferred immediately to the filling line for packaging. Therefore, viscosity testing is only required on the finished product samples.

Please note on the original ANDA, page 1544, states that the last day of inspection was May 25, 1999. The correct date should be May 2–5, 1999.

Should you have any comments or require any further clarification on this amendment, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax:** (718) 960-0111

Sincerely,

Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

August 21, 2001

Michelle Dillahunt, Project Manager
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA FPL
ORIG AMENDMENT

MINOR AMENDMENT

RE: ANDA 76-067 Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Dillahunt:

In reference to the deficiency letter for the Chemistry, Labeling and Bioequivalency sections dated June 21, 2001 **(Attachment 1)** on our abbreviated new drug application for Mometasone Furoate Ointment USP, 0.1% ANDA # 76-067, Clay-Park Labs, Inc. hereby submits the deficiency response for the Chemistry Manufacturing and Control and Labeling sections designated as a Minor Amendment.

We acknowledge that the Division of Bioequivalence has completed the review of our submission and has no further questions at this time.

Should you have any comments or require any further clarification on this amendment, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax:** (718) 960-0111

Sincerely,

Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

March 23, 2001

Krista Scardina
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II, HFD-615
7500 Standish Place, Room 150
Rockville, MD 20855

NEW CORRESP

Re: Correspondence to ANDA # 76-067 for Mometasone Furoate Ointment USP, 0.1%

Dear Ms. Scardina:

As per our telephone conversation on March 22, 2001, please find the correct data diskette for the Vasoconstrictor Study # 10016924 conducted by on Mometasone Furoate Ointment USP, 0.1%.

Should you have any questions, please call the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
MAR 26 2001
OGD

Candis Edwards
Director of Regulatory Affairs

Enclosure: computer diskette

1 of 4

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

76-067

January 26, 2001

Mr. Gary Buehler, Acting Director
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II, HFD-600
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NEW CORRESP

RE: Electronic Submission for Mometasone Furoate Ointment USP, 0.1%, ANDA

Dear Mr. Buehler:

In support of the hard copy of the ANDA for Mometasone Furoate Ointment USP, 0.1%, we are hereby submitting two copies of the electronic submission of the Chemistry, Manufacturing and Control (CMC) section. The CMC electronic submission includes the following files, which are contained on one (1) diskette:

File Name	Document
Cpl0004.003	CMC ESD File
Cpl0004.lgc	Log File
Cpl0004.004	Companion Document including Table of Contents

The diskettes and a Declaration Statement are contained in the blue (Archival Copy) jacket, Form FDA 2626.

Please note that during the data entry in Entry Validation Application (EVA) for the electronic submission, discrepancies were noted in the hard copy of the ANDA. They have been corrected in the electronic submission document (ESD) and in the companion document, and are as follows:

- 'Statement of Labeling Similarity', This title was missing from page 0019 of the hard copy of the original ANDA submission

- On pages 0022, 0023 and Table of Contents of the hard copy, the grade of White Beeswax, (White Wax, NF) was mistakenly listed as The correct grade of White Beeswax, (White Wax, NF) is NF
- On page 0029, 4.a.*ii* of the hard copy of the original ANDA, the statement "...whereas innovator did not..." the correct statement should read as follows "...whereas innovator did..."

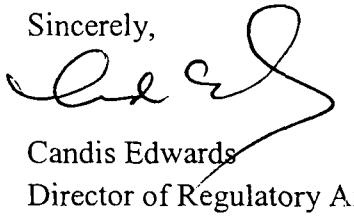
- Please note that on page 0022 of the hard copy, the grade of White Beeswax, (White Beeswax, NF) was mistakenly listed as grade. The correct grade of White Beeswax, (White Beeswax, NF) is NF
- On page 0043 of the hard copy of the original ANDA, the storage conditions for Clay-Park Labs, Inc.'s Mometasone Furoate Ointment USP, 0.1% was incorrectly listed as "...between ..." The correct storage conditions was "...between 2 and 30°C (36° and 86°F)...".

- Please note at the time of filing of the ANDA Submission, we did not receive the DMF number from the FDA. Subsequently we have updated this information in the EVA Companion Document and the Electronic Submission. The DMF number

Should you have any questions, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,



Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

December 21, 2000

Mr. Gary Buehler, Acting Director
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II, HFD-600
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: ANDA for Mometasone Furoate Ointment USP, 0.1%

Dear Mr. Buehler:

Clay-Park Labs, Inc. hereby submits an original abbreviated new drug application (ANDA) in hard copy format to be followed by electronic format, to seek approval to market Mometasone Furoate Ointment USP, 0.1% that is bioequivalent to the reference listed drug, Elocon® (mometasone furoate ointment) Ointment 0.1%, manufactured by Schering Corporation pursuant to NDA # 019543.

This ANDA consists of eight (8) volumes. Clay-Park Labs, Inc. is filing an archival copy (in blue folders) of the ANDA that contains all the information required in the ANDA and a technical review copy (in red folders) that contains all the information in the archival copy with the exception of the bioequivalence section (VI). A separate copy of the bioequivalence section is provided in orange folders.

This also certifies that, concurrently with the filing of this ANDA, a true copy of the technical section of the ANDA (including a copy of the 356h form and a certification that the contents are a true copy of those filed with the Office of Generic Drugs) is being sent to our local district office. This "field copy" is contained in burgundy folders.

For a more detailed information on the organization of this ANDA, please refer to the "Executive Summary" attached after the field copy certification statement.

Clay-Park Labs, Inc. will submit CMC ESD electronic submission (diskettes) for Mometasone Furoate Ointment USP, 0.1% as new correspondence within the 30 day grace period.

Should you have any comments or require any further clarification on this ANDA, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax:** (718) 960-0111

Thank you for your prompt handling of this submission.

Sincerely,

Candis Edwards
Director of Regulatory Affairs