

**CENTER FOR DRUG  
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RESEARCH**

**APPLICATION NUMBER:**

**40-420**

**CORRESPONDENCE**

ORIGINAL



Regulatory Affairs  
Morton Grove Pharmaceuticals, Inc.  
6451 West Main Street  
Morton Grove, Illinois 60053

Phone (847) 967-5600  
Fax (847) 583-5052

September 29, 2000

*Via Federal Express*

Gary J. Buehler, Acting Director  
Office of Generic Drugs, CDER  
Food and Drug Administration  
Document Control Room 150  
Metro Park North II  
7500 Standish Place  
Rockville, MD 20857-2773

Re: Original ANDA for Phenytoin Oral Suspension, USP 125 mg/5 mL  
(MGP Product Code 8131)

Dear Mr. Buehler,

In accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act, Morton Grove Pharmaceuticals, Inc., (MGP) has today submitted by courier an original Abbreviated New Drug Application (ANDA) seeking approval to market **Phenytoin Oral Suspension, USP 125 mg/5 mL** that is bioequivalent to the reference listed drug, Dilantin-125<sup>®</sup> manufactured by Parke-Davis, pursuant to NDA #008762.

Morton Grove Pharmaceuticals, Inc., is requesting permission to manufacture **Phenytoin Oral Suspension, USP 125 mg/5 mL** in            batches with an expiration dating period of 24 months from the date of manufacture in the container/closure systems listed in this application.

This application includes CMC and BA/BE electronic submissions. We are enclosing electronic diskette (ASCII format), containing the concentration and pharmacokinetic data files for the subject bioavailability study (fda.1.). We are also enclosing herewith the electronic BA/BE submission consisting of 2 diskettes, containing the clinical, pharmacokinetic and analytical ESD files, data files, and companion document in the format required by the FDA for electronic submissions. The electronic CMC submission will be forwarded to the Agency as a new correspondence within 30 days.

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# ORIGINAL

Gary J. Buehler, Director  
September 29, 2000  
Page 2

**This ANDA consists of six (6) volumes.** As required under 21 CFR 314.94, MGP is filing three copies of this application:

- an archival copy (in blue folders) of the ANDA that contains all the information required for an ANDA,
- a technical review copy (in red folders) which contains all the information in the archival copy, with the exception of the Bioequivalence Section (VI),
- a separate technical review copy of the Bioequivalence Section (VI) (in orange folders), and
- concurrently with the filing of this ANDA, a true copy of the technical sections 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 the Chicago District Office. This "field copy" is contained in burgundy folders.

We are also enclosing on pages 000003 to 000004 copy of the letter forwarded to Mr. Raymond V. Mlecko, Director, Chicago District Office, FDA.

All materials stamped 'confidential' are considered proprietary information and should not be released under the Freedom of Information Act.

Morton Grove Pharmaceuticals, Inc., commits to resolve any issues identified in the methods validation process after approval.

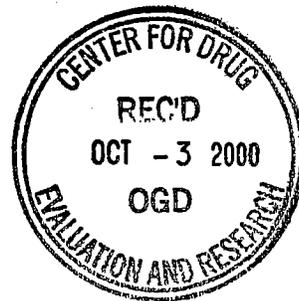
For more detailed information on the organization of this ANDA, please refer to the attached Executive Summary, 'Organization of the ANDA'. Please direct any communications regarding this ANDA to me at the above address. If you need to call or fax me, the numbers are (847) 967-5600 (phone) and (847) 583-5052 (fax).

Thank you for your prompt handling of this submission.

Sincerely,



Yogita Desai, Director  
Regulatory Affairs



*Encl.*

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40-420

mef RS



**ORIGINAL**

October 26, 2000

Regulatory Affairs  
Morton Grove Pharmaceuticals, Inc.  
6451 West Main Street  
Morton Grove, Illinois 60053  
Phone (847) 967-5600  
Fax (847) 583-5052

*Via Federal Express*

**NEW CORRESP**  
NC

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

**Re: CMC Electronic Submission for Phenytoin Oral Suspension, USP 125 mg/5 mL**  
**(MGP Product Code 8131)**

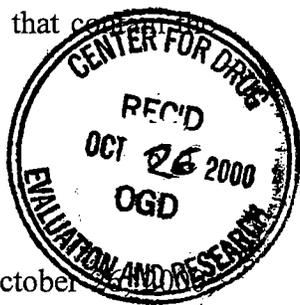
Dear Mr. Buehler:

Morton Grove Pharmaceuticals, Inc., (MGP) hereby submits the CMC Electronic Submission for **Phenytoin Oral Suspension, USP 125 mg/5 mL**. The subject diskette is enclosed.

The original Abbreviated New Drug Application (ANDA) seeking approval to market **Phenytoin Oral Suspension, USP 125 mg/5 mL**, was submitted to the FDA on September 29, 2000. The BA/BE Electronic Submission was forwarded on September 29, 2000. Copies of cover letters of the original application and the BA/BE electronic submission are also enclosed.

This CMC Electronic Submission consists of 1 diskette (archival copy) that contains the following files:

CMC Electronic Submission Document	MGP0002.003
CMC Companion Document	MGP0002.004
CMC EVA Log File	MGP0002.lgc



The information contained in this CMC electronic submission dated October 26, 2000 for **Phenytoin Oral Suspension, USP 125 mg/5 mL**, is not different from the information contained in the hard copy submission dated September 29, 2000 for **Phenytoin Oral Suspension, USP 125 mg/5 mL**, except for the Tables noted in the companion document.

**000001**

Gary J. Buehler, Acting Director  
October 26, 2000  
Page 2

MGP acknowledges that:

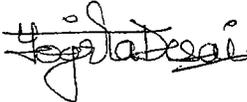
- formatting restrictions may change the appearance of information.
- the archive submission is complete while the ESD/Companion Document is not.
- typographical errors are handled as they are currently handled.

Notification regarding the CMC Electronic Submission has been sent to Mr. Raymond Mlecko, Director, Chicago District Office, FDA (copy enclosed).

Please direct any communications regarding this CMC Electronic Submission to me at the above address. If you need to call or fax me, the numbers are (847) 967-5600 (phone) and (847) 583-5052 (fax).

Thank you for your prompt handling of this submission.

Sincerely,



Yogita Desai  
Director, Regulatory Affairs

Enclosures

000002

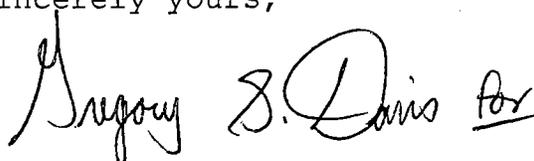




Upon receipt of this communication, you may either amend your application to correct the deficiencies or withdraw your application under 21 CFR 314.99. If you have any questions please call:

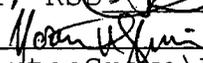
Martin Shimer  
Project Manager  
(301) 827-5862

Sincerely yours,



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

cc: ANDA 40420  
DUP/Jacket  
Division File  
HFD-92  
Field Copy  
HFD-610/R.West  
HFD-610/P.Rickman  
HFD-615/Mbennett

Endorsement: HFD-615/NMahmud, Chief, RSB  date 27-Nov-20  
HFD-615/MShimer, CSO  date 11/27/00  
Word File V:\Firmam\MortonGrove\Ltrs&rev.40420rtf  
F/T File  
ANDA Refuse to Receive!



February 02, 2001

Via Federal Express

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

Regulatory Affairs  
Morton Grove Pharmaceuticals, Inc.  
6451 West Main Street  
Morton Grove, Illinois 60053

Phone (847) 967-5600  
Fax (847) 583-5052

505 (A) OK  
J  
FEB-2001  
Gregory B. Desai

ORIGINAL

ORIG AMENDMENT

N/A/C

RE: ANDA # 40-420, Phenytoin Oral Suspension 125 mg/5 mL  
MGP Product Code 8131  
Amendment in Response to Refusal to File Letter, Rickman to Desai,  
dated December 6, 2000

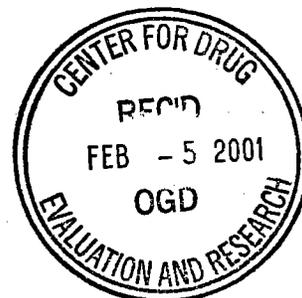
Dear Mr. Buehler:

Pursuant to Peter Rickman's letter of December 6, 2000 (copy enclosed), Morton Grove Pharmaceuticals, Inc. (MGP) hereby amends the original ANDA #40-420, **Phenytoin Oral Suspension 125 mg/5 mL**. A complete copy of this amendment is being sent to Raymond V. Mlecko, Director, Chicago District Office, FDA. For your convenience, our responses are preceded by your comments.

If you have any further questions, please call me at (847) 967-5600.

Sincerely,

AniMa Katragadda  
for Yogita Desai,  
Director, Regulatory Affairs



000001





ORIGINAL

July 20, 2001

Regulatory Affairs  
Morton Grove Pharmaceuticals, Inc.  
6451 West Main Street  
Morton Grove, Illinois 60053  
Phone (847) 967-5600  
Fax (847) 583-5052

Via Airborne Express

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

RECEIVED

ORIG. AMENDMENT  
N/AB

RE: **ANDA # 40-420, Phenytoin Oral Suspension, USP 125 mg/5 mL**  
**MGP Product Code 8131**  
**Bioequivalency Amendment in Response to Deficiency Letter,**  
**Conner, FDA to Desai, MGP dated June 20, 2001**

Dear Mr. Buehler:

The sponsor, Morton Grove Pharmaceuticals, Inc. (MGP), is providing this amendment to address the bioequivalency comments identified in the letter dated June 20, 2001 (copy enclosed) for ANDA # 40-420, Phenytoin Oral Suspension, USP 125 mg/5 mL. A complete copy of the amendment was sent to Raymond V. Mlecko, Director, Chicago District Office, FDA.

For your convenience, our responses are preceded by your comments.

If you have any questions, please call me at 847-967-5600.

Thank you for your attention to this matter.

Sincerely,

Yogita Desai  
Regulatory Affairs



Encl.

000001



September 20, 2001

Regulatory Affairs  
Morton Grove Pharmaceuticals, Inc.  
6451 West Main Street  
Morton Grove, Illinois 60053  
Phone (847) 967-5600  
Fax (847) 583-5052

*Via Airborne Express*

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

**ORIGINAL**

ORIG AMENDMENT  
N/A M

**RE: ANDA # 40-420, Phenytoin Oral Suspension, USP 125 mg/5 mL  
(MGP Product Code 8131)  
Minor Amendment in Response to Chemistry Deficiency Letter,  
Fang, FDA to Desai, MGP dated April 27, 2001**

Dear Mr. Buehler:

The sponsor, Morton Grove Pharmaceuticals, Inc. (MGP), is providing this amendment to address the chemistry comments identified in the letter dated April 27, 2001 (copy enclosed). This letter included both CMC and Bioequivalency comments. Responses for the Bioequivalency comments were submitted to the Agency on July 20, 2001.

A complete copy of this amendment is being sent to Raymond V. Mlecko, Director, Chicago District Office, FDA.

For your convenience, our responses are preceded by your comments.

If you have any questions, please call me at 847-967-5600.

Thank you for your attention to this matter.

Sincerely,

Yogita Desai  
Regulatory Affairs



*Encl.*

000001

**ORIGINAL**



February 22, 2002

Regulatory Affairs  
Morton Grove Pharmaceuticals, Inc.  
6451 West Main Street  
Morton Grove, Illinois 60053  
Phone (847) 967-5600  
Fax (847) 583-5052

*Via Federal Express*

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

*N/mm*  
**ORIG AMENDMENT**

*Noted.*  
*To*  
*Yanping*  
*M Anderson*  
*2/28/02*

**RE: ANDA # 40-420, Phenytoin Oral Suspension, USP 125 mg/5 mL  
(MGP Product Code: 8131)**

- **Minor Amendment in Response to Deficiency Letter from Fang, FDA to Desai, MGP dated November 13, 2001**
- **Other CMC Revision**

Dear Mr. Buehler:

The sponsor, Morton Grove Pharmaceuticals, Inc. (MGP), is providing this amendment to address the chemistry comments identified in the letter from Fang, FDA, to Desai, MGP, dated November 13, 2001 (copy enclosed) and notify of other CMC revision.

A complete copy of this amendment is being sent to Mr. Arlyn H. Baumgarten, Acting Director, Chicago District Office, FDA.

For your convenience, our responses are preceded by your comments.

If you have any questions, please call me at 847-967-5600.

Thank you for your attention to this matter.

Sincerely,

Yogita Desai  
Regulatory Affairs



*Encl.*

000001

*MW*  
*2/26/02*