CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:74-986

CORRESPONDENCE

MARTEC
SCIENTIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

Telephone Amendment to ANDA 74-986

February 8, 1999

NDA ORIG AMENDMENT
N/FM

Mr. Doug Sporn
Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600 – RM 278
7500 Standish Place
Rockville, MD 20855-2773

RE: Telephone Amendment to ANDA 74-986 for Diclofenac Sodium Delayed-release Tablets USP, 50 mg and 75 mg.

Dear Mr. Sporn:

In response to telephone deficiencies (Mr. Mark Anderson, 2/8/99) from OGD, and in accordance with 21 CFR 314.96, Martec Scientific, Inc. herewith submits a **Telephone** amendment to the above-mentioned ANDA. A facsimile copy of the entire response is also provided to Mr. Mark Anderson, CSO, OGD.

Two copies of the entire response are provided (1 volume each) as archival and review copies. The firm's response and attachments are provided as ***APPENDIX I.***

Please contact me at (816) 241-4144 or at 800-822-6782, if you need additional information.

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President/COO
Martec Scientific, Inc.

Enclosures
APPENDIX I – Firm's Response

MARTEC
SCIENTIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY MO 64120 3510

MINOR Amendment to ANDA 74-986

January 5, 1999

Mr. Doug Sporn
Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600 – RM 278
7500 Standish Place
Rockville, MD 20855-2773

RE: MINOR Amendment to ANDA 74-986 for Diclofenac Sodium Delayed-release Tablets USP, 50 mg and 75 mg.

Dear Mr. Sporn:

In response to the Minor deficiency letter (received by fax) of December 28, 1998 from, OGD, and in accordance with 21 CFR 314.96, Martec Scientific, Inc. herewith submits a **MINOR** amendment to the above-mentioned ANDA. A facsimile copy of the entire response is also provided to Mr. Mark Anderson, CSO, OGD.

Two copies of the entire response are provided (1 volume each) as archival and review copies . A copy of the not approvable letter is presented as ***APPENDIX I*** and the firm's response is provided as ***APPENDIX II***.

Please contact me at (816) 241-4144 or at 800-822-6782, if you need additional information.

Sincerely,

Paul T. Sudhakar
President/COO
Martec Scientific, Inc.

Enclosures
APPENDIX I – Deficiency letter of December 28, 1998.
APPENDIX II – Response to Deficiency letter of December 28

MARTEC
SCIENTIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

MINOR Amendment to ANDA 74-986

ORIG AMENDMENT
N/AM

November 27, 1998

Mr. Doug Sporn
Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600 – RM 278
7500 Standish Place
Rockville, MD 20855-2773

RE: MINOR Amendment to ANDA 74-986 for Diclofenac Sodium Delayed-release Tablets USP, 50 mg and 75 mg.

Dear Mr. Sporn:

In response to the Minor deficiency letter (received by fax) of November 23, 1998 from, OGD, and in accordance with 21 CFR 314.96, Martec Scientific, Inc. herewith submits a **MINOR** amendment to the above-mentioned ANDA. A facsimile copy of the entire response is also provided to Mr. Mark Anderson, CSO, OGD.

The chemistry & manufacturing deficiency in the OGD letter of November 23, 1998 is addressed in this amendment. Acknowledgement of the bioequivalence comment is also provided. Two copies of the entire response are provided (1 volume each) for archive and review. A copy of the not approvable letter is presented as ***APPENDIX I*** and the firm's response is provided as ***APPENDIX II***.

Please contact me at (816) 241-4144 or at 800-822-6782, if you need additional information.

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President/COO
Martec Scientific, Inc.

Enclosures
APPENDIX I – Deficiency letter of November 23, 1998.
APPENDIX II – Response to Deficiency letter of November 23, 1998

NOV 30 1998

MARTEC
SCIENTIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

VIA ORIG AMENDMENT
AF

TELEPHONE Amendment to ANDA 74-986

February 24, 1998

Mr. Doug Sporn
Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600 – RM 278
7500 Standish Place
Rockville, MD 20855-2773

RE: TELEPHONE Amendment to ANDA 74-986 for Diclofenac Sodium Delayed-release Tablets USP, 50 mg and 75 mg.

Dear Mr. Sporn:

Pursuant to a telephone message from Mr. Chen Park of the labeling division and in accordance with 21 CFR 314.96, Martec Scientific, Inc. herewith submits a **TELEPHONE** amendment to the above-mentioned ANDA.

The package insert submitted in the amendment of 2/14/98 contains an inadvertent revision to the dosage regimen for the Rheumatoid Arthritis indication. Pursuant to Mr. Park's telephone call we have revised the package insert to indicate the correct dosage regimen.

12 copies of the final printed insert (2 sets, one for archival and one for review) are provided.

Please contact me at (816) 241-4144 or at 1-800-822-6782, if you need additional information.

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President/COO
Martec Scientific, Inc.

RECEIVED
FEB 25 1998

1. **1 set of 12 inserts for Review**
2. **1 set of 12 inserts for Archival**

MARTEC
SCIENTIFIC, INC.
[illegible] TOPPING
P.O. BOX [illegible]
KANSAS CITY, MO [illegible]

MAJOR Amendment to ANDA 74-986

June 15, 1998

ORIG AMENDMENT

1/F

Mr. Doug Sporn
Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600 – RM 278
7500 Standish Place
Rockville, MD 20855-2773

RE: MAJOR Amendment to ANDA 74-986 for Diclofenac Sodium Delayed-release Tablets USP, 50 mg and 75 mg.

Dear Mr. Sporn:

In response to the major deficiency letter (received by fax) of May 27, 1998 from, OGD, and in accordance with 21 CFR 314.96, Martec Scientific, Inc. herewith submits a **MAJOR** amendment to the above-mentioned ANDA.

All the chemistry & manufacturing deficiencies of the OGD letter of May 27, 199 are addressed in this amendment. Two copies of the entire response are provided (1 volume each) for archive and review. A copy of the not approvable letter is presented as ***APPENDIX I*** and the firm's response is provided as ***APPENDIX II***.

Please contact me at (816) 241-4144 or at 800-822-6732 if you need additional information.

RECEIVED
JUN 16 1998
GENERIC DRUGS

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President/COO
Martec Scientific, Inc.

Enclosures
APPENDIX I – Deficiency letter of May 27, 1998.
APPENDIX II – Response to Deficiency letter of May 27, 1998

MARTEC
SCIENTIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-0510

NOTED 7/21/97

NEW CORRESP
BIOAVAILABILITY

NC/EC

June 26, 1997

Mr. Douglas Sporn, Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600
7500 Standish Place
Rockville, MD 20855

RE: Amendment to Pharmacokinetics section - ANDA 74-986 – Diclofenac sodium delayed-release tablets 50 mg and 75 mg

Per telephone request of Ms. Lizzie Sanchez of June 17th 1997.

Dear Mr. Sporn:

Pursuant to a telephone request of June 17, 1997 by Ms. Lizzie Sanchez of Division of Bioequivalence (OGD), Martec Scientific, Inc. is hereby amending the Pharmacokinetics section for Abbreviated New Drug Application 74-986 for ***Diclofenac sodium delayed-release tablets, 50 mg and 75 mg tablets***.

Please contact me if you need additional information.

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President, MSI.

Enclosures

1. **1 Set for Archival copy of Pharmacokinetics**
2. **1 Set for Review copy of Pharmacokinetics**

RECEIVED
JUN 27 1997
GENERIC DRUGS

7-1-97

PRIVATE OFFICE (816) 241-4144 ▪ FAX MACHINE (816) 483-5432 ▪ SALES & MARKETING (800) 822-6732

Response to information requested by Ms. Sanchez by telephone on June 17, 1997.

1. **Individual plasma concentrations and Mean plasma concentrations:**

   For study CPR 96-801 (50 mg single dose fasted - full study)
   Please see Volume I of the 50 mg report pages 397 to 425. Some pages (5-18) are missing in the original copy. The entire information is resubmitted in this amendment as *Attachment 1.*

   For Study CPR 96-802 – (75 mg single dose fasted - full study)
   Please see volume 1 of 75 mg report – Module II, pages 443 to 448, which are resubmitted, as *Attachment 2.*

   For Study CPR 96-803 - (75 mg single dose limited food effect study) - Please see volume 3 of the 75 mg report – Module II, pages 1640 to 1674 which are resubmitted as *Attachment 3.*

2. **Statistical reports:**

   For study CPR 96-801 (50 mg single dose fasted - full study)
   Please see volume 3 of the 50 mg report – Module IV, pages 1363 to 1381, which are resubmitted as *Attachment 1a.*

   For Study CPR 96-802 – (75 mg single dose fasted - full study)
   Please see volume 3 of 75 mg report – Module IV, pages 1423 to 1442, which are resubmitted as *Attachment 2a.*

   For Study CPR 96-803 - (75 mg single dose limited food effect study) - Please see Volume 4 of the 75 mg report – Module IV, pages 2281 to 2284 which are resubmitted as *Attachment 3a.*

   These reports presented as Module II for the individual data and as Module IV for the statistical reports are also provided on floppy diskette for all three studies as follows:

   50 mg single dose fasted – file name: 801Fr2.exe
   75 mg single dose fasted – file name: 802Fr2.exe
   75 mg single dose limited food effect study – file name: 803Fr2.exe

   These files which are compressed as *.exe, may be inflated and opened in MS Word as follows:

   1. **In MS DOS prompt copy the file to your preferred directory or disk drive**
   2. **IN MS DOS prompt type the file name and hit <enter>**

3. Exit MS DOS when inflation is complete
(Each of files is inflated into two files containing module II (Individual data) and Module IV (Statistical reports)
4. The files can now be opened in MS Word
(This data is also presented in the Archival and Review copies for ANDA 74-986, which are available with you)

3. For full pharmacokinetics report of 75 mg limited food effect study – please see Volume 3 of the 75 mg study, Attachment 7, beginning with page 1602.

4. The Raw Data in the following format

File #1: SUBJ SEQ PER TRT AUCOT AUCIN CMAX
File #2: SUBJ SEQ PER TRT CONC1-N

is presented in ASCII format on 3 diskettes, one for each of the studies:

Disk 2: Study CPR 96-801 Diclofenac Na delayed release tablets 50 mg – Single dose fasted study

Disk 3: Study CPR 96-802 Diclofenac Na delayed release tablets 75 mg – Single dose fasted study

Disk 3: Study CPR 96-803 Diclofenac Na delayed release tablets 75 mg – Single dose limited food effect study.

Hard copy of the data is also presented as *Attachment 4*

4. The tables of contents for the archival and review copies are revised for better presentation.

The revised main table of contents and the table for contents for each of the sections in the bioreport are provided as *Attachments 5 (for 50 mg report) and 5a (for 75 mg report)*

Please contact me by telephone if this response does not satisfactorily resolve all issues mentioned by Ms. Lizzie Sanchez.

Thank you.

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President, MSI.

ARTEC
TIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

MAJOR Amendment to ANDA 74-986

N/AC

August 22, 1997

Mr. Doug Sporn
Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600 – RM 278
7500 Standish Place
Rockville, MD 20855-2773

RE: MAJOR Amendment to ANDA 74-986 for Diclofenac Sodium Delayed-release tablets USP, 50 mg and 75 mg.

Dear Mr. Sporn:

In response to the major deficiency letter of July 22, 1997 from, OGD, and in accordance with 21 CFR 314.96, Martec Scientific, Inc. herewith submits an amendment to the above-mentioned ANDA.

All the chemistry, manufacturing and labeling deficiencies and comments of the OGD letter of July 22, 1997 (presented as ***Attachment 1***) are addressed in this amendment. Two copies are provided (1 volume each) for archival and review.

Please contact me at (816) 241-4144 or at 1-800-822-6782, if you need additional information.

Sincerely,

Paul T. Sudhakar

Paul T. Sudhakar
President/COO
Martec Scientific, Inc.

1. **356h Form**
2. **Enclosures**
   Attachment 1 – Deficiency letter of July 22, 1997 .
   Attachments 2 – Response to Deficiency letter of July 22, 1997
   Attachments 3 to 19 – Response to various comments

MARTEC
SCIENTIFIC, INC.
[illegible] TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

BIOAVAILABILITY Note 7/21/97

June 10, 1997

Mr. Douglas Sporn, Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD 600
7500 Standish Place
Rockville, MD 20855

NEW CORRESP

RE: ANDA 74-986 – Diclofenac sodium delayed-release tablets 50 mg and 75 mg
Additional copies of Archival and Review sections of – resubmission per (URGENT) request of Ms. Lizzy Sanchez.

Dear Mr. Sporn:

Pursuant to a telephone request of June 9, 1997 by Ms. Lizzy Sanchez of Division of Bioequivalence (OGD), Martec Scientific, Inc. is hereby resending copies of section for Abbreviated New Drug Application 74-986 for ***Diclofenac sodium delayed-release tablets, 50 mg and 75 mg tablets***.

Ms. Lizzy Sanchez indicated to me that the request for additional set of copies is due to accidental shredding of part of the Original ANDA at OGD.

This submission contains the following Archival and the Review copies of the Bioequivalence study report:

Report for 50 mg product (ANDA 74-986)

Two copies – 3 volumes each for the full study of the 50 mg product under fasting conditions with a request for waiver of the limited food effect study on the basis of the food effect study carried out with the 75 mg product.

Study Number: CPR 96-801-

Report for 75 mg product (ANDA 74-986)

Two copies – 4 volumes each for the full study of the 75 mg product under fasting conditions and a limited food effect study.

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JUN 12 1997
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CORPORATE OFFICE (816) 241-4144 ■ FAX MACHINE (816) 483-5432 ■ SALES & MARKETING (800) 822-6782

Study numbers: CPR 96-802 (fasted study) and CPR 96-803 (limited food effect study)

Computer diskettes:

One computer diskettes for each study with files compressed for all modules of the study report.

CPR 96-801 – 50 mg fasted study
CPR 96-802 – 75 mg fasted study
CPR 96-803 - 75 mg limited food effect study

Please contact me if you need additional information.

Sincerely,

Paul T. Sudhakar
President, MSI.

enclosures

1. **Archival copy of 50 mg (3 volumes)**
2. **Review copy of s 50 mg (3 volumes)**
3. **Archival copy of s 75 mg (4 volumes)**
4. **Review copy of s 75 mg (4 volumes)**
5. **Computer diskettes**

MARTEC
SCIENTIFIC, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY MO 64120-3510

February 24, 1997

Mr. Doug Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
MPN II, HFD 600
7500 Standish Place
Rockville, MD 20855

RE: New Information to ANDA 74-986 for Diclofenac Sodium Delayed-release Tablets, 50 mg and 75 mg.

Dear Mr. Sporn:

A typographical error has been discovered on page 1542 of ANDA 74-986 submitted by Martec Scientific, Inc., for Diclofenac Sodium Delayed-release tablets 50 mg and 75 mg. The error has been corrected and two copies of the corrected page are provided in this communication. This typographical error does not alter any material information nor any calculations provided in the original submission.

Sincerely,

Paul T. Sudhakar
President/COO

Enclosure: 1 copy of the page 1542 from original submission (with error identified)
2 copies of corrected pages numbered as 1542 (rev).
1 Copy of the batch record page (from ANDA) to support the corrected figure.

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FEB 26 1997
GENERIC DRUGS

Page(s) 4

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Executed Batch Records

File 74-986

MARTEC
PHARMACEUTICAL, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

December 2, 1996

Office of Generic Drugs
CDER, FDA
Attn: Mr. Douglas Sporn.
MPN II, HFD 600
7500 Standish Place
Rockville, MD 20855

BIOAVAILABILITY
NEW CORRESP
NC BIO

Dear Mr. Sporn:

In accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act, Martec Scientific, Inc., Kansas City, MO 64120 submitted separate Abbreviated New Drug Applications for ***Diclofenac sodium delayed-release tablets, 50 mg and 75 mg tablets***.

We are amending the ANDA for the 75 mg (74-986) into a single application for both the 50 mg and the 75 mg product. This submission contains the Bioequivalence/Bioavailability study report (3 volumes) versus the reference product Voltaren[R] 50 mg (Geigy) under fasting conditions (full study) with a request for waiver of the limited food effect study based on the study carried out with the 75 mg product filed as an ANDA on October 10, 1996. ANDA number 74-987.

Sincerely,

Paul T. Sudhakar
Sr. Vice President Scientific Affairs

enclosures

1. **Archival copy of Pharmacokinetics (3 volumes)**
2. **Review copy of Pharmacokinetics (3 volumes)**
3. **Amendment letter for ANDA 74-987**

RECEIVED
DEC 04 1996

(816) 241-4144 CORPORATE OFFICE
(800) 822-6782 SALES & MARKETING
(816) 483-5432 FAX MACHINE

MARTEC
PHARMACEUTICAL, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

December 1, 1996

Mr. Douglas Sporn:
Office of Generic Drugs
MPN II, HFD 600, Room 280
7500 Standish Place
Rockville, MD. 20855

Amendment to ANDA 74-987 for Diclofenac sodium delayed release tablets, 75 mg.

Dear Mr. Sporn:

Due the fact that this product requires fasted biostudy for each drug product with a waiver of food effect study for the 50 mg product, Martec filed the original application as two separate ANDAs. Pursuant to communication from Ms. Anna Marie Weikel of OGD and information provided by her, we wish to combine the submissions into one ANDA.

Martec hereby amends the 75 mg original submission to a combined application for both the 50 mg and 75 mg products (Letter withdrawing the 50 mg application is enclosed). Revised cover letter and form 356h to reflect this change are provided. This change request will not require any resubmission of Chemistry and Manufacturing Controls (CMC) documents by Martec because the application submitted for the 75 mg product contains all the CMC information required for the 50 mg drug product, however we are resending an archival copy and a review copy of the bioequivalence study for the 50 mg product with a request for waiver of the limited food study.

Please contact me at 816-241-4144 or 1-800-822-6782, if you should need additional information.

Sincerely,

Paul T. Sudhakar
Sr. V.P. Scientific Affairs
Martec Scientific, Inc.

enclosures: 1. Revised cover letter
2. Revised 356h forms
3. Bioequivalence study (fasted) for 50 mg drug product with waiver request for the limited food

12/5/96 - D requested an original 356h w/ this W/D request. - AMWeikel

MARTEC
PHARMACEUTICAL, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

12/20/96 CF

December 1, 1996

74-987 = 50mg WID

NEW CORRESP

Mr. Douglas Sporn:
Office of Generic Drugs
MPN II, HFD 600, Room 280
7500 Standish Place
Rockville, MD. 20855

Withdrawal of ANDA 74-986 for Diclofenac sodium delayed release tablets, ~~50~~ 75 mg.

Dear Mr. Sporn:

Due the fact that this product requires fasted biostudy for each drug product with a waiver of food effect study for the 50 mg product, Martec filed the original application as two separate ANDAs. Pursuant to communication from Ms. Anna Marie Weikel of OGD and information provided by her, we wish to combine the submissions into one ANDA.

Martec hereby withdraws the original filing of the application of the 50 mg drug product because we are amending the 75 mg application into a combined application for both the 50 mg and 75 mg products (Letter amending the 75 mg application and revised 356h forms enclosed). This change will not require any resubmission of Chemistry and Manufacturing Controls (CMC) documents by Martec because the original application submitted for the 75 mg product contains all the CMC information required for the 50 mg product, however we are resending an archival copy and a review copy of the bioequivalence study for the 50 mg product with request for waiver of the food study as an amendment to the 75 mg application (ANDA 74-986).

Please contact me at 816-241-4144 or 1-800-822-6782, if you should need additional information.

Sincerely,

Paul T. Sudhakar
Sr. V.P. Scientific Affairs
Martec Scientific, Inc.

RECEIVED
DEC 04 1996

enclosure: Amendment cover letter to ANDA 74-987

(816) 241-4144 CORPORATE OFFICE
(800) 822-6782 SALES & MARKETING
(816) 483-5432 FAX MACHINE

MARTEC
PHARMACEUTICAL, INC.
1800 N. TOPPING
P.O. BOX 33510
KANSAS CITY, MO 64120-3510

October 10, 1996

Office of Generic Drugs
CDER, FDA
Attn: Douglas Sporn M.D.
MPN II, HFD 600
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Sporn:

In accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act, Martec Scientific, Inc., Kansas City, MO 64120 is submitting an Abbreviated New Drug Application for ***Diclofenac sodium delayed-release tablets, 75 mg***. Each copy (Archival and Review) of this submission contains 8 volumes, 4 for the Chemistry and Manufacturing and 4 for the Pharmacokinetics sections. A field copy (4 volumes) of the Chemistry and Manufacturing section has been forwarded to the Kansas City, Field Office, with the required certification that it is an exact true copy of the Archival copy.

The submission contains the Chemistry and Manufacturing Controls (CMC) the completed Bioequivalence/Bioavailability study report (4 volumes) versus the reference product Voltaren[R] 75 mg (Geigy) under fasting conditions (full study) and a limited food effect study.

The Chemistry and Manufacturing Section for the 50 mg product and the 75 mg product is identical, however Archival and Review copies are provided for both applications (50 mg and 75 mg). Review of one full CMC part of the application will provide all the required CMC information for both the 50 mg product and the 75 mg product.

Sincerely,

Paul T. Sudhakar
Sr. Vice President Scientific Affairs.

enclosures

1. **Archival copy of CMC (4 volumes)**
2. **Review copy of CMC (4 volumes)**
3. **Archival copy of Pharmacokinetics (4 volumes)**
4. **Review copy of Pharmacokinetics (4 volumes)**

(816) 241-4144 CORPORATE OFFICE
(800) 822-6782 SALES & MARKETING
(816) 483-5432 FAX MACHINE

ANDA 74-986

Martec Scientific, Inc.
Attention: Paul T. Sudhakar
1800 N. Topping, Avenue
P.O. Box 33510
Kansas City, MO 64120-3510

FEB 10 1997

Dear Sir:

Please refer to your abbreviated new drug application (ANDA) dated October 10, 1996, submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Diclofenac Sodium Delayed-release Tablets, 50 mg and 75 mg.

We also refer to your correspondence dated December 1, December 2, and December 5, 1996.

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to file this ANDA under 21 CFR 314.101(d)(3) for the following reasons:

> Regarding the test batch #960103 for diclofenac sodium delayed-release tablets 50 mg , please provide additional documentation which confirms that the portion of the test batch that was packaged is representative of the entire test batch. Such documentation should include results of in-process testing, a sampling protocol, and a statement that the partial packaging procedure was performed in compliance with the Office of Generic Drugs Policy and Procedure Guide #41-95. In addition, please provide the results of an investigation regarding the rejection of approximately one-fourth of your test batch (as set out on p.1542) and information that the remaining portion of the test batch meets your release specifications.

Thus, it will not be filed as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Please be advised that you are required to package the entire test batch in the containers proposed for marketing. Please refer to the Office of Generic Drugs Policy and Procedure Guide #41-95 for Guidance on the Packaging of Test Batches.

In addition, please submit three additional copies of the analytical methods and descriptive information needed to perform the tests on the samples (both the bulk active ingredient(s) and

finished dosage form) and validate the analytical methods. Please do not send samples unless specifically requested to do so. If samples are required for validation, we will inform you where to send them in a separate communication.

If the above methodology is not submitted, the review of the application will be delayed.

Within 30 days of the date of this letter you may amend your application to include the above information or request in writing an informal conference about our refusal to file the application. To file this application over FDA's protest, you must avail yourself of this informal conference.

If after the informal conference, you still do not agree with our conclusion, you may make a written request to file the application over protest, as authorized by 21 CFR 314.101(a)(3) If you do so, the application shall be filed over protest under 21 CFR 314.101(a)(2). The filing date will be 60 days after the date you requested the informal conference. If you have any questions please call:

Anna Marie H. Weikel
Project Manager
(301) 594-0315

Sincerely yours,

/S/

Jerry Phillips 2/10/97
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research