CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-926

CORRESPONDENCE

ALPHARMA
U.S. Pharmaceuticals Division

March 26, 1999

[illegible] AMENDMENT

Office of Generic Drugs
CDER, Food and Drug Administration
Attn.: Mr. Douglas Sporn, Director
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: **ANDA 74-926**
M-Zole 3 Combination Pack
(Miconazole Nitrate Vaginal Suppositories USP, 200mg and Miconazole Nitrate Cream USP, 2%)

TELEPHONE AMENDMENT TO A TENTATIVELY APPROVED APPLICATION

Dear Mr. Sporn:

Pursuant to 21 CFR 314.96(a), Alpharma, U.S. Pharmaceuticals Division, herein submits an amendment to the above referenced application. We make reference to the March 11, 1999 telephone conversation between Dr. Paul Schwartz of the FDA and Ronald Bynum of Alpharma. The subject of this conversation was Alpharma's January 29, 1999 tentative approval amendment for the M-Zole 3 Combination Pack application.

The Agency's comment has been paraphrased and Alpharma's response follows:

Both the cream and suppository components of this drug product should have in-process limits of with a relative standard deviation (RSD) of not more than

Enclosed in this amendment, you will find revised Product Testing Monographs for both the Miconazole Nitrate Vaginal Suppositories USP, 200mg and Miconazole Nitrate Cream, USP which support the Agency's request. To the suppository monograph we have tightened the limits on the In-Process Product Analysis Report from " " to ', and added the specification for RSD with a limit of not more than (NMT)
The cream monograph was revised to add the Bulk Product Analysis Report which includes assay testing of samples from the top, middle, and bottom of the batch tank with limits of and a RSD of

RECEIVED
MAR 29 1999
GENERIC DRUGS

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Alpharma USPD Inc.
Research & Development Center
Johns Hopkins Bayview Campus
333 Cassell Drive, Suite 3500
Baltimore, MD 21224
Tel (410) 558-7250
Fax (410) 558-7258

In accordance with 21 CFR 314.96(b), Alpharma certifies that the field copy is a true copy of this amendment and has been sent to the Atlanta, GA FDA district office.

We trust that our response fully addresses the Agency's concerns.

Sincerely,
Alpharma USPD Inc.

Ronald Bynum
Manager, Regulatory Affairs

RB:ah
Enclosures

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333 Cassell Drive, Suite 3500
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ALPHARMA
U.S. Pharmaceuticals Division

January 29, 1999

FPL

NDA UNIT MANAGEMENT

Office of Generic Drugs
CDER, Food and Drug Administration
Attn.: Mr. Douglas Sporn, Director
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: **ANDA 74-926**
M-Zole 3 Combination Pack
(Miconazole Nitrate Vaginal Suppositories USP, 200mg and Miconazole Nitrate Cream USP, 2%)

MINOR AMENDMENT TO A TENTATIVELY APPROVED APPLICATION

Dear Mr. Sporn:

As instructed in the Agency's tentative approval letter (enclosed) dated June 23, 1998 and pursuant to 21 CFR 314.96(a), Alpharma, U.S. Pharmaceuticals Division, herewith submits a minor amendment for subject ANDA. The Agency's letter states in part,

> "Please provide the Agency, at least 60, but not more than 90 days prior to April 16, 1999, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated as a MINOR AMENDMENT in your cover letter...Please be advised that you are required to submit 12 final printed copies of all labels and labeling as part of the minor amendment noted above."

In this amendment we are providing updated chemistry, manufacturing, and controls data and final printed labeling. We have enclosed each of the updated documents, and a comparison of the updated document to the version previously submitted in this application.

Alpharma acknowledges that prior to issuance of the final approval letter by the Agency,

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Alpharma USPD Inc.
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our 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". We also note that the Agency reserves the right to request further changes in the labels and/or labeling based upon changes to the approved labeling of the listed drug or upon further review of the application prior to approval.

In accordance with 21 CFR 314.96(b), Alpharma certifies that the field copy is a true copy of this minor amendment and has been sent to the Atlanta, GA FDA district office.

We trust that our response fully addresses the Agency's concerns.

Sincerely,
Alpharma USPD Inc.

Ronald Bynum

Ronald Bynum
Manager, Regulatory Affairs

RB:ah
Enclosures

K:\759\REGFILES\PRODUCTS\7310\SUBMISS\TENTAPVL.AMA

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ALPHARMA
U.S. Pharmaceuticals Division

April 20, 1998

ORIG AMENDMENT

Office of Generic Drugs
CDER, Food and Drug Administration
Attn.: Mr. Douglas Sporn, Director
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: **ANDA #74-926**
Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (M-Zole 3 Combination Pack)

TELEPHONE AMENDMENT TO A PENDING APPLICATION

Dear Mr. Sporn:

Pursuant to 21 CFR § 314.96(a), Alpharma USPD hereby submits a telephone amendment to our pending ANDA for Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (M-Zole 3 Combination Pack). Reference is made to the telephone deficiencies communicated on April 10 & 13, 1998 by Mr. Joseph Buccine from FDA, OGD concerning drug product stability testing.

The Agency's comments have been restated and our responses follow.

1. **Please provide clarification for the memo on page 639 of the 02/13/98 amendment to the application. In the last paragraph of the memo there is a statement that the expiration dating was supported by a 6 months 30° C stability protocol. Is six months expiry dating for the drug product being requested?**

   The intent of the memo on page 639 of the 02/13/98 amendment to the application was to provide the rationale for not performing dissolution testing on the suppository samples from the 40° C accelerated stability study.

333 Cassell Drive, Suite 3500
Baltimore, MD 21224

GENERIC DRUGS

The requested expiration dating for this drug product is 24 months, as noted on page 249 of the 02/13/98 amendment to the application. Since the memo on page 639 of the 02/13/98 amendment to the application was intended to address dissolution testing, reference to expiration dating was actually inappropriate. Therefore, we have removed this paragraph from the memo. A copy of the revised memo is enclosed as page 4.

2. **Please provide any additional stability data that are available. Please supply both room temperature and 30° C data, if available.**

At this time, we only have additional stability data for the suppository dosage form from the 6 months room temperature stability station (page 5). Additional room temperature data for both the cream and suppository dosage forms will be available later. The 30° C stability study was a 6 months study for the suppository dosage form and the study has been completed. The data were previously submitted as page 638 of the 02/13/98 amendment to the application.

We trust that our response adequately addresses the issues raised by the Agency's April 10 & 13, 1998 telephone deficiencies.

In case of any questions or additional concerns, please call me at 410-558-7250 extension 208 or send a facsimile to my attention at 410-558-7258.

In accordance with 21 CFR § 314.96(b), Alpharma USPD certifies that the field copy is a true copy of the telephone amendment to the application and has been sent to the FDA Atlanta, GA district office.

Sincerely,
ALPHARMA USPD INC.

Ronald Bynum

Ronald Bynum
Manager, Regulatory Affairs
RB:rb
Enclosures

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ALPHARMA
U.S. Pharmaceuticals Division

Miconazole Nitrate Cream USP, 2% and
Miconazole Nitrate Vaginal Suppositories USP , 200 mg
(M-Zole 3 Combination Pack)

ANDA #74-926

TELEPHONE AMENDMENT TO A PENDING APPLICATION

In accordance with 21 CFR 314.96(b), Alpharma certifies that the field copy is a true copy of this Telephone Amendment and has been sent to the Atlanta, GA FDA District Office.

Ronald Bynum
Ronald Bynum
Manager, Regulatory Affairs

4/20/98
Date

k:\...\7310\submiss\041098td.ama

Alpharma USPD Inc.
Research & Development Center
The Johns Hopkins Bayview Center
333 Cassell Drive, Suite 3500
Baltimore, MD 21224
Tel (410) 558-7250
Fax (410) 558-7258

ALPHARMA
U.S. Pharmaceuticals Division

April 3, 1998

N/A M

Office of Generic Drugs
CDER, Food and Drug Administration
Attn.: Mr. Douglas Sporn, Director
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: **ANDA# 74-926**
Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP , 200mg (M-Zole 3 Combination Pack)

TELEPHONE AMENDMENT TO A PENDING APPLICATION

Dear Mr. Sporn:

Pursuant to 21 CFR § 314.96(a), Alpharma USPD hereby submits a telephone amendment for our pending ANDA for Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP , 200mg (M-Zole 3 Combination Pack)

Reference is made to the telephone deficiency communicated on March 27 & 30, 1998 by Mr. Joseph Buccine from FDA, OGD concerning the drug substance manufacturers utilized in this ANDA.

The Agency's comments have been restated and our responses follow.

1. **What is the DMF Number for the Miconazole Nitrate USP drug substance manufactured by Erregierre?**

Alpharma USPD Inc.
Research & Development Center
The Johns Hopkins Bayview Center
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Baltimore, MD 21224
Tel (410) 558-7250
Fax (410) 558-7258

Page(s) 1

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

4/3/98

3. **One exhibit batch is needed for each drug substance manufacturer utilized for each dosage form included in the M-Zole 3 Combination Pack (including packaging, certificates of analysis, and stability data). Please make reference as to where this data is located if it has already been submitted to the application, and submit the data which have not been previously submitted.**

Exhibit batches are provided in the 2/13/98 amendment to subject application for each of the two drug substance manufacturers utilized to support the submission. As described in the table which follows, Miconazole Nitrate Cream USP, 2%, was manufactured using drug substance. The executed batch record (batch #600/576-L538) including packaging is found on pages 416-466. The Certificate of Analysis (Lot #L610086) is located on page 628, and the accelerated and room temperature stability data are found on pages 634 and 641, respectively. Miconazole Nitrate Vaginal Suppositories USP, 200mg, were manufactured using drug substance. The executed batch record (Batch #700/590-L549) including packaging is found on pages 467-499. The Certificate of Analysis (Lot #L706097) is located on pages 631-632, and the accelerated and room temperature stability data are found on pages 636-639 and 643, respectively.

	Executed Batch Record (Pages)	Certificate of Analysis (Pages)	Accelerated Stability (Pages)	Room Temperature Stability (Pages)
Miconazole Nitrate Cream USP, 2%	416-466	628	634	641
Miconazole Nitrate Vaginal Suppositories USP, 200mg	467-499	631-632	636-639	643

NOTE: Page number indicates location of information in the 2/13/98 amendment to ANDA# 74-926 (M-Zole 3 Combination Pack).

We trust that our response adequately addresses the issues raised by the Agency's March 27 & 30, 1998 telephone deficiency.

In case of any questions or additional concerns, please call me at 410-558-7250 extension 208 or send a facsimile to my attention at 410-558-7258.

In accordance with 21 CFR § 314.96(b), Alpharma USPD certifies that the field copy is a true copy of the telephone amendment to the application and has been sent to the FDA Atlanta, GA district office.

Sincerely,
ALPHARMA USPD INC.

Ronald Bynum

Ronald Bynum
Manager, Regulatory Affairs
RB:ah
Enclosures
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ALPHARMA
U.S. Pharmaceuticals Division

BIOAVAILABILITY

February 13, 1998

Office of Generic Drugs
CDER, FDA
Attn: Douglas Sporn, Director
Document Control Room
Metro Park North II
7500 Standish Place, Room #150
Rockville, MD 20855-2773

BYC Label
ORIG AMENDMENT
jm

Re: ANDA # 74-926
Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (M-Zole 3 Combination Pack)

AMENDMENT TO A PENDING APPLICATION

Dear Mr. Sporn:

Pursuant to 21 CFR 314.96(a), Alpharma, U.S. Pharmaceuticals Division (formerly NMC Laboratories, Able Laboratories, and Barre-National) herewith submits an amendment for M-Zole 3 Combination Pack (Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP, 200 mg), ANDA#74-926. Reference is made to our ANDA submission dated July 15, 1996, the August 14, 1996 amendment, and the Agency's letters dated September 13, December 6, 1996, and January 15, 1997.

Reference is made to ANDA#74-586 (Alpharma's M-Zole 7 Dual Pack) for which a similiar amendment was approved on July 17, 1997.

Also, we make reference to the two approved ANDAs for the individual drug products from which this ANDA is based, ANDA #74-164 for Miconazole Nitrate Vaginal Cream, 2%, and ANDA #73-508 for Miconazole Nitrate Vaginal Suppositories USP, 200mg.

Upon submission of the original ANDA dated July 15, 1996, Alpharma had intended to use Miconazole Nitrate Cream USP, 2.0% manufactured at Alpharma-NMC's facility in Glendale, NY, and Miconazole Nitrate Vaginal Suppositories USP, 200 mg manufactured at Alpharma owned Able Laboratories in South Plainfield, NJ. Alpharma has since sold Able Laboratories to DynaGen, Inc. (August 19, 1996), and closed NMC Laboratories (March 27, 1997).

As described in the July 15, 1996 cover letter to this ANDA, we have based this application on the two approved ANDAs for the individual components which make up the combination pack; (1) ANDA #74-164 (Miconazole Nitrate Vaginal Cream, 2%), and (2) ANDA #73-508 (Miconazole Nitrate Vaginal Suppositories USP, 200mg).

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Alpharma USPD Inc.
Research & Development Center
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Tel (410) 558-7250
Fax (410) 558-7258

With this amendment we are seeking approval to manufacture both the Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (The drug products contained in subject M-Zole 3 Combination Pack) at our manufacturing facility in Lincolnton, NC. The Lincolnton manufacturing facility has already been approved for the individual ANDA products, ANDA #74-164 (Miconazole Nitrate Vaginal Cream, 2%) in Supplements 001, 002, 003, and 004 on October 18, 1996, and the facility was approved for ANDA #73-508 (Miconazole Nitrate Vaginal Suppositories USP, 200 mg) in supplements 004, 005, 006, and 009 on July 24, 1996. Throughout this amendment we will frequently make reference to these two ANDAs (74-164 & 73-508) and their approved supplements.

Alpharma-Lincolnton's address follows:

Alpharma, U.S. Pharmaceutical Division
1877 Kawai Road
Lincolnton, North Carolina 28092

We are also seeking to withdraw from the application the following drug product manufacturers which were previously submitted:

NMC Laboratories Inc.
70-36 83rd Street
Glendale, New York 11385

and

Able Laboratories Inc.
6 Hollywood Court
South Plainfield, New Jersey 07080

Section I entitled, "Summary of Proposed Changes" describes the changes, relative to the approved individual ANDA products, proposed in this amendment which will allow Alpharma to manufacture the M-Zole 3 Combination Pack drug product at our Lincolnton facility. We will also address the deficiencies received in the January 15, 1997 letter from FDA (enclosed). The deficiencies are addressed in the following locations:

Chemistry	
Deficiency Number	Response (pages)
A.1	250, 335
A.2	500, 576
A.3	041, 238
A.4	041,190,238,241
A.5	005
A.6	041,190,238,241
A.7	005

Labeling	
Deficiency Number	Response (Pages)
1.a	See 2a,3a,4a
1.b	See 2a,3a,4a
2.a	666
2.b	N/A
3.a	668
3.b	669
4.a	672
4.b	672

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ALPHARMA
U.S. Pharmaceuticals Division

We have enclosed in section VI of this amendment four copies of draft labeling for the suppository foil, insert, and carton; and, we have enclosed twelve copies of the final printed labeling for the tube. Alpharma understands that the agency reserves the right to request further changes in labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval. In accordance with 21 CFR 314.94 (a)(8)(iv) and to facilitate review of this submission we have provided a side-by-side comparison of the revised labeling with the labeling submitted in our last submission with all differences annotated and explained.

We acknowledge that the firms referenced in the application relative to the manufacture and testing of the product must be in compliance with cGMP(s) at the time of approval of the application. In addition, Alpharma acknowledges that USP methods are the regulatory methods and will prevail in the event of dispute.

This submission consists of 3 volumes. Volumes 1 and 2 contain subject amendment, and volume 3 contains two additional copies of the method validation reports.

Pursuant to 21 CFR 314.96 (b), Alpharma certifies that the field copy is a true copy of this amendment to the application and has been sent to FDA's Atlanta, GA district office.

Sincerely,
Alpharma

Ronald Bynum
Manager, Regulatory Affairs

RB:ah

cc: Atlanta District Office

Alpharma USPD Inc.
Research & Development Center
The Johns Hopkins Bayview Center
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NMC LABORATORIES INC.

NEW CORRESPONDENCE
505(b)(2)(a) info
acceptable for filing
Annemarie Weikel
5/19/96

RECEIVED

AUG 19 1996

GENERIC DRUGS

Deborah Miran no longer is employed by NMC, Ron Bynum has become the new agent

August 14, 1996

Douglas Sporn, Director
Office of Generic Drugs, CDER
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

Re: **Abbreviated New Drug Application**
Miconazole Nitrate Cream USP, 2%, and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (combination package)

AMENDMENT TO A PENDING APPLICATION

Dear Mr. Sporn:

Pursuant to 21 CFR 314.96 (a) (1), NMC Laboratories Inc., herewith submits an amendment to the Abbreviated New Drug Application for the above mentioned drug product. Reference is made to the telecommunication which occurred on August 9, 1996 between AnnaMarie Weikel of the Food and Drug Administration and Ron Bynum of ALPHARMA. To comply with the Administration's request, we have enclosed a revised exclusivity statement which addresses applicable marketing exclusivity for the reference listed drug. In addition, we have included additional physical-chemical comparative data for the drug product and the reference listed drug.

Pursuant to 21 CFR 314.96 (b), NMC certifies that the field copy is a true copy of this amendment to the application and has been sent to the Brooklyn, New York district FDA office.

Sincerely,

NMC LABORATORIES, INC.

Deborah Miran
Senior Director, Regulatory Affairs

DM/ckj

\NMC\PRODUCTS\734\SUBMISS\AMENDT.PEN

70-36 83rd Street, Glendale, NY 11385 • (718) 326-1500
Fax Numbers 1-800-255-7588 (Outside New York State)
718-894-3218 (Within New York State)

ANDA 74-926

NMC Laboratories, Inc.
Attention: Deborah Miran
333 Cassell Drive
Suite 3500
Baltimore MD 21224

DEC - 6 1996

Dear Madam:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Miconazole Nitrate Cream USP, 2% and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (Combination Package).

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

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

Rabindra Patnaik, Ph.D.
Acting Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

NMC LABORATORIES INC.

July 15, 1996

RECEIVED

JUL 16 1996

GENERIC DRUGS

Douglas Sporn, Director
Office of Generic Drugs, CDER
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

Re: **Abbreviated New Drug Application**
Miconazole Nitrate Cream USP, 2%, and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (combination package)

Dear Mr. Sporn:

NMC herewith submits an Abbreviated New Drug Application pursuant to 21 CFR 314.94(a) and Section 505(j) of the Federal Food, Drug and Cosmetic Act for the drug product Miconazole Nitrate Cream USP, 2%, and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (combination package).

The Miconazole Nitrate Cream USP, 2%, and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (combination package) ANDA is based on NMC Laboratories' approved application # 73-508 for Miconazole Nitrate Vaginal Suppositories, USP 200 mg (approved 11/19/93) and NMC Laboratories' approved application # 74-164 for Miconazole Nitrate Vaginal Cream, 2% (approved 3/29/96). Although NMC Laboratories is the holder of ANDA # 73-508 for Miconazole Nitrate Vaginal Suppositories, USP 200 mg, this product will be manufactured at Able Laboratories. Able Laboratories Inc. located in South Plainfield, New Jersey and NMC Laboratories, Inc. located in Glendale, New York are both wholly owned subsidiaries of the parent company, ALPHARMA $_{TM}$.

Throughout this ANDA, NMC Laboratories is regarded as the holder of this ANDA, and Able Laboratories is referred to as a contract firm. Also, in various areas of this application, NMC's Miconazole Nitrate External Vulvar Cream 2% is referred to as Miconazole Nitrate Vaginal Cream 2% as well as Miconazole Nitrate Antifugal Cream 2%.

The Miconazole Nitrate Cream USP, 2%, and Miconazole Nitrate Vaginal Suppositories USP, 200 mg (combination package) application contains original data from production batches, and it also references general information previously submitted in the #74-164 and # 73-508 applications. Where previously submitted information is referenced, photocopies of the information is provided in order to make the combination package application complete, and the fact that photocopied information has been provided is noted. The combination package application relies on the bioequivalence studies previously submitted and approved for Miconazole Nitrate Vaginal Suppositories, 200 mg (ANDA #73-508) and previously submitted for Miconazole Nitrate Vaginal Cream, 2% (ANDA # 74-164).

70-36 83rd Street, Glendale, NY 11385 • (718) 326-1500
Fax Numbers 1-800-255-7588 (Outside New York State)
718-894-3218 (Within New York State)

The abbreviated application is being submitted as follows:

1) Archival Copy (Blue Folder) - consisting of three volumes which contain items required for an ANDA per 21 CFR section 314.94(a) plus all the information required under section 505(j)(2)(A)(B) of the FD&C Act (see Table of Contents of this application).

2) Review Copy - which contains items for an ANDA per 21 CFR 314.94(d)(2) in two separate sections:

   Red Folder- Items described under 314.94(a)(2) through (a)(6), (a)(8), (a)(9), analytical methods, and analytical methods validation contained in three volumes.

   Orange Folder- Items described under 314.94(a)(3), (a)(7), and (a)(8).

3) Non-Compendial Methods (Blue Folder) - which contains two (2) copies of non-compendial methods.

Pursuant to 21 CFR 314.94 (d), NMC certifies that the field copy is a true copy of this abbreviated application and has been sent to the Brooklyn, New York district FDA office.

Sincerely,

NMC LABORATORIES, INC.

Deborah Miran
Senior Director, Regulatory Affairs
DM/ckj
\nmc\..\734\coverlet.2