CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-951

CORRESPONDENCE

Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

NDA ORIG AMENDMENT

N/AM

August 26, 1998

Office of Generic Drugs, CDER, FDA
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: ANDA 74-951; Butalbital 50mg/Aspirin 325mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP

'TELEPHONE AMENDMENT'

Dear Ms. Florence Fang:

As per our telephone conversation on 8/26/98, please find enclosed the analytical method for the noted drug product. This method describes how impurities/degradents are calculated.

As per our discussion, we will continue testing beyond the first three validation batches. Once significant data has been generated, we will submit a supplement to have this testing terminated.

If I can be of further assistance, please contact me at (516) 567-1113

Sincerely,

William Cardone

William Cardone
Scientific Director

RECEIVED

AUG 28 1998

GENERIC DRUGS

Sixty DaVinci Drive • Bohemia, New York 11716 • Phone: (516) 567-1113 • Fax: (516) 567-1189

JSP

ANDA 74-988

Jerome Stevens Pharmaceuticals, Inc.
Attention: Ronald Steinlauf
60 DaVinci Drive
Bohemia, NY 11716

JAN 27 1997

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 our "Refuse to File" letter dated January 3, 1997, and your amendment dated January 16, 1997. We also refer to your correspondence dated December 3, and December 12, 1996.

NAME OF DRUG: Orphenadrine Citrate, Aspirin, and Caffeine Tablets, 25 mg/385 mg/30 mg and 50 mg/770 mg/60 mg

DATE OF APPLICATION: October 21, 1996

DATE OF RECEIPT: October 22, 1996

DATE ACCEPTABLE FOR FILING: January 16, 1997

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

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

Should you have questions concerning this application contact:

Tim Ames
Project Manager
(301) 594-0305

Sincerely yours,

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

Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

labeling review drafted 7/30/98 A. Vazzo

VIA ORIG AMENDMENT

June 4, 1998

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

RE: ANDA 74-951; Butalbital 50mg/Aspirin 325mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP

'MINOR AMENDMENT'

Dear Sir/Madam,

This is a reply to your letter dated May 4, 1998:

1. Response to container/closure system deficiencies:

a. Please refer to pgs. 2-5. These pages contain results of the Container Permeation Test, USP 23 [671] for the container/closure systems used for the drug product. Page #3 has the data for Lot 015395, 500 count bottle and Lot 007196, 100 & 500 count bottle. Page #5 has the data for Lot 015395, 100 count bottle.

b. The cap used for the 180cc bottle (100's size) was a 45mm metal screwcap, for lot # 015395 and a 45mm plastic screwcap was used on the 180cc bottle (100's size), for lot # 007196. Both the 45mm metal screwcap and the 45mm plastic screwcap have a liner.

The cap used for the 750cc bottle (500's size) was a 53mm metal screwcap, for lot # 015395 and a 53mm plastic screwcap was used on the 750cc bottle (500's size), for lot #007196. Both the 53mm metal screwcap and the 53mm plastic screwcap have a liner.

c. The cap liners (liner) are composed of foam with a coating. The is no inner safety seal used in the container/closure system for this drug product.

d. Please refer to pg. 6 for a concise revised summary of container/closure systems used for this drug product.

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JUN 0 5 1998

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Jerome Stevens Pharmaceuticals
Inc.
Generic Manufacturers

2. Please refer to pgs. 7-14 for updated stability testing reports, Accelerated and Long-Term, for both 100 and 500 container sizes. These reports now contain tests and specifications for unknown, known and total known & unknown impurities/degradents.

3. As per our telephone conversation with Mr. Tim Ames on May 20, 1998, following approval of the application, we will place the first production batch under accelerated stability conditions for testing at 30, 60 and 90 days. We will perform dissolution testing using the current procedure and using the procedure specified in the 20th IRA to USP 23 published in the Pharmacopeial Forum, Volume 23, #6, Nov. - Dec. 1997. The comparison of this dissolution data will enable us to establish the nature of the pellicule formation observed with this product.
   We will submit this data to the Agency for review.

4. Please see pgs. 15-42 for room temperature stability data for Lot: 007196. This data is up to 24 months and includes dissolution data. Room temperature stability data for Lot: 015395 can be found on pgs. 245-253 of our original submission and pgs. 195-204 of our amendment to this application dated 9/29/97.

Labeling Deficiencies:

1. Please refer to pgs. 43-60 which contain three (12) copies of final printed container and insert labeling with the revisions requested. The archival copy (blue) contains twelve (12) copies of final printed container and insert labeling. They can be found on pages 43-114 of the archival copy (blue).

Sincerely,

Ronald Steinlauf

Ronald Steinlauf
Vice President

Sixty DaVinci Drive • Bohemia, New York 11716 • Phone: (516) 567-1113 • Fax: (516) 567-1189

ANDA 74-951

MAY 4 1998

38. Chemistry Comments to be Provided to the Applicant

ANDA: 74-951 APPLICANT: Jerome Stevens Pharmaceuticals Inc.

DRUG PRODUCT: Butalbital, Aspirin, Caffeine and Codeine Phosphate Capsules USP , 50 mg/325 mg/40 mg/30 mg

The deficiencies presented below represent MAJOR deficiencies.

Chemistry Deficiencies:

1. In regard to the container/closure system, we have the following comments:

   a. Please submit results of USP 23 <671> Containers-Permeation for both container/closure systems.

   b. Please describe more clearly the cap used for each bottle. It is unclear as to whether the cap for the 180cc bottle is plastic or metal.

   c. Please describe more clearly the composition of the cap liners for each bottle and the inner safety seal if used.

   d. Please submit a concise revised summary of the container/closure systems used for this drug product. This summary should include all applicable information regarding the closure components, materials, manufacturers etc.

2. Please submit a revised stability testing report form which included the tests and specifications for individual and total degradation products (refer to pp. 114 - 115 of your September 29, 1997 amendment).

3. Please perform dissolution testing at accelerated conditions using the procedure specified in the 20th IRA to USP 23 published in the Pharmacopeial Forum, Volume 23, # 6, Nov. - Dec. 1997.

4. Please submit all room temperature stability data for dissolution testing that has been accrued to date for the finished drug product.

Sincerely yours,

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

38. Chemistry Comments to be Provided to the Applicant

ANDA: 74-951 APPLICANT: Jerome Stevens Pharmaceuticals Inc.

DRUG PRODUCT: Butalbital, Aspirin, Caffeine and Codeine Phosphate Capsules USP , 50 mg/325 mg/40 mg/30 mg

The deficiencies presented below represent MAJOR deficiencies.

Chemistry Deficiencies:

1. In regard to the container/closure system, we have the following comments:

   a. Please submit results of USP 23 <671> Containers-Permeation for both container/closure systems.

   b. Please describe more clearly the cap used for <u>each</u> bottle. It is unclear as to whether the cap for the 180cc bottle is plastic or metal.

   c. Please describe more clearly the composition of the cap <u>liners</u> for each bottle and the <u>inner safety seal</u> if used.

   d. Please submit a concise revised summary of the container/closure systems used for this drug product. This summary should include all applicable information regarding the closure components, materials, manufacturers etc.

2. Please submit a revised stability testing report form which included the tests and specifications for individual and total degradation products (refer to pp. 114 - 115 of your September 29, 1997 amendment).

3. Please perform dissolution testing at accelerated conditions using the procedure specified in the 20th IRA to USP 23 published in the Pharmacopeial Forum, Volume 23, # 6, Nov. - Dec. 1997.

4. Please submit all room temperature stability data for dissolution testing that has been accrued to date for the finished drug product.

Sincerely yours,

5/1/98

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

NDA ORIG AMENDMENT

N/AC

September 29, 1997

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

RE: ANDA 74-951; Butalbital 50mg/Aspirin 325mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP

'MAJOR AMENDMENT'

Dear Sir/Madam,

This is a reply to your letter dated June 9, 1997:

1. Response to active ingredient deficiencies:

Aspirin:

a. Please refer to pgs 1-2. These COA contain the OVI testing results.

b. Please refer to pg. 3-4.

c. Please refer to pg. 5 for the revised Aspirin USP COA.

d. Please refer to pg. 1. This COA contains results of those tests that are not conducted by JSP. The results from both COA's meet full compendial testing.

Butalbital:

a. Please refer to pg. 6. This COA contains the results of the OVI testing.

b. Please refer to pg. 7.

Caffeine:

a. Please refer to pg. 8.

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OCT 0 1 1997
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General comments regarding active ingredients:

a. Please refer to pgs. 1,2,6,9-12 for the COAs that contain the results for those test not conducted by

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JSP. The results from both COA meet full compendial testing for all of the active ingredients.

b. Firm will establish the reliability of our supplier's analyses through confirmation of our supplier's tests results at appropriate intervals.

c. Please refer to pgs. 13-15 for the updated COAs for the active ingredients.

d. Please refer to pg. 16 which will amend pg. 117 of our original submission. Firm has changed our retest period to 18 months.

2. Inactive ingredients:

a. Please refer to pgs. 17 & 18 for the updated COAs

b. Please refer to pg. 19 for a composition statement regarding the hard gelatin capsule.

c. Please refer to pgs. 20-23 which contain a DMF authorization letter from Capsugel for DMF
is the hard gelatin capsule manufacturer. We also included product specifications from the manufacturer of the ink. The manufacturer is
and they supply the ink to

3. Manufacturing process and controls:

a. Please refer to pg. 24 which amends pg. 128 of our original submission.

b. This is an area that the firm has addressed during the post-approval process validation phase of the manufacturing procedures.

c. Please refer to pg. 25 which revises the ingredient weight sheet.

d. Please refer to pgs. 26-37 which contain comparative assay and dissolution data from our method and the USP 23 method.

e. Please refer to pgs. 38-54 which contains the Method Validation report and data for our method.

f. Due to storage considerations and cost, we packaged

only those 100 count bottles needed to conduct our stability studies.

g. Please refer to pg. 55 which amends pg. 126 of our original submission.

4. Stability testing protocol and procedures:

a. Please refer to pgs. 59-113 which contains data from a study which includes forced degradation data which demonstrates that our method is suitability for stability testing purposes.

b. Please refer to pg. 56 which amends pg. 218 of our original submission.

c. Please refer to pg. 56.

d. Please refer to pgs. 57-58 which revises our accelerated stability protocol to include dissolution testing.

e. Firm has a temperature/humidity recorder monitoring the long term stability samples. Firm stores the long term stability samples under ambient humidity conditions. Review of the charts show a range of 30-80% relative humidity over a 12 month period. The mean relative humidity is about 60%.

f. Firm has conducted accelerated dissolution testing on lot #015395, please see pgs. 125-138

g. Firm conducted a study to evaluate this drug product for degradation products other than free Please see pgs. 59-113. Results of this study show that our method used for the assay of this drug product is stability indicating and can be used to monitor for degradation products. Analysis of long term stability sample (2 years) and accelerated stability sample show no degradation products other than free Firm proposes a limit of for both individual known and unknown degradation products and a limit of for total known and unknown degradation products, excluding free salicylic acid.

h. Firm has revised its limit for free on long term stability testing to Please refer to pgs. 114-115.

i. Please refer to pgs. 116-138 for comparative dissolution data at accelerated conditions for our drug product and Fiorinal with Codeine.

5. Container/closure:

a. Please refer to pgs. 139-143 for testing conducted on the 180cc container from Container. Please refer to pgs. 144-150 for testing conducted on the 750cc container from Plastics.

b. Please refer to pgs 151-153 for COA and a letter of authorization to DMF from

c. The colorant used for the 180cc bottle was White.

d. Please refer to pgs. 154-155 for letter of authorization for DMF nd technical data from the manufacturer of the cap liner supplied to
Please refer to pg 156 for the letter of authorization for DMF from , the manufacturer of the plastic caps. Please refer to pgs. 157-158 for the letter of authorization for DMF nd a product data sheet from the manufacturer of the cap liner supplied to The liner used in not an inner tamper resistant seal.

TEKNIPLEX MANUFACTURES THE PS22

e. Please refer to pgs. 159 & 160 for letter of authorization for DMF from the manufacturer's of resins, respectively.

f. Please refer to pgs. 161-166 for the engineering drawings for the bottles and caps.

g. The closures are not two piece Child Resistant Closures. The description refers to a cap made of either plastic or metal. ?? WHICH IS USED ?

h. The cap manufacturers used were

WHICH ONE MAKES WHICH CAP ??

i. Please refer to pgs. 167-168.

j. There is a Drug Master File authorization letter for DMF on pg. 167 of our original submission.

k. Please refer to pg. 169.

6. Please refer to pg. 170 which amends pg. 256 of our original submission.

Labeling Deficiencies:

1. Please refer to pgs 171-194 which contain four (4) copies of draft container and insert labeling with the revisions requested.

Supplemental Data:

1. Firm is submitting Long-Term Stability Data (18 & 24 months) for Lot # 015395 as was stated on pg 219 of our original submission. Please refer to pgs. 195-204 for this data.

If I can be of further assistance, please contact me at (516) 567-1113

Sincerely,

Ronald Steinlauf
Vice President

1.1
Shostak, D

ANDA 74-951

MAY 2 1997

Jerome Stevens Pharmaceuticals, Inc.
Attention: Ronald Steinlauf
60 DaVinci Drive
Bohemia NY 11716

Dear Sir:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Aspirin, Butalbital, Caffeine, Codeine Phosphate Capsules USP, 50 mg/325 mg/40 mg/30 mg.

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

2. The dissolution testing will need to be incorporated into your stability and quality control programs as specified in USP 23.

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,

for Nicholas Fleischer, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

NEW CORRESP

BIOAVAILABILITY

April 2, 1997

Office of Generic Drugs, CDER, FDA
Attn: Ms. Saundra Middleton
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: ANDA 74-951; Butalbital 50mg/Aspirin 325mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP

Dear Ms. Middleton:

Here is the information you requested as per our telephone conversation on 4/2/97:

- The label claim for the Reference Listed Drug and Submitted Drug Product is Butlbital 50mg/Aspirin 325mg/ Caffeine 40mg/Codeine Phosphate 30mg Capsule. This information can also be found in Bioavailability/Bio-equivalence part of the application in SECTION 6, volume 1, the Summary section (pg 2).

-The batch size for drug product used bioequivalence study is capsules (Lot #: 015395).

If I can be of further assistance, please contact me at (516) 567-1113

Sincerely,

Ronald Steinlauf
Vice President

RECEIVED

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Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

April 10, 1997

Office of Generic Drugs, CDER, FDA
Attn: Ms. Saundra Middleton
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: ANDA 74-951; Butalbital 50mg/Aspirin 325mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP

Dear Ms. Middleton:

Here is the information you requested as per our telephone conversation on 4/8/97:

- Enclosed please find a certificate of analysis of the reference lot for the above application.

If I can be of further assistance, please contact me at (516) 567-1113

Sincerely,

William Cardone

William Cardone
Scientific Director

Sixty DaVinci Drive • Bohemia, New York 11716 • Phone: (516) 567-1113 • Fax: (516) 567-1189

38. Chemistry Comments to be Provided to the Applicant

ANDA: 74-951 APPLICANT: Jerome Stevens

DRUG PRODUCT: Butalbital, Aspirin, Caffeine and Codeine Phosphate Capsules USP

The deficiencies presented below represent MAJOR deficiencies.

Chemistry Deficiencies:

1. In regard to the active ingredients, we have the following comments:

Page(s) 2

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

Chem. Comments

2/9/97

6. Your environmental impact statement should include a claim for a categorical exclusion per 21 CFR 25.24 (c)(1).

Sincerely yours,

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

38. Chemistry Comments to be Provided to the Applicant

ANDA: 74-951 APPLICANT: Jerome Stevens

DRUG PRODUCT: Butalbital, Aspirin, Caffeine and Codeine Phosphate Capsules USP

The deficiencies presented below represent MAJOR deficiencies.

Chemistry Deficiencies:

1. In regard to the active ingredients, we have the following comments:

Page(s) 2

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

Chem. Comments.

6/5/97

[illegible] preparation and packing.

6. Your environmental impact statement should include a claim for a categorical exclusion per 21 CFR 25.24 (c)(1).

Sincerely yours,

6/5/97

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 74-951

Jerome Stevens Pharmaceuticals, Inc.
Attention: Ronald Steinlauf
Sixty DaVinci Drive
Bohemia, NY 11716

DEC 27 1996

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 our "Refuse to File" letter dated November 20, 1996, and to your amendment dated November 26, 1996.

NAME OF DRUG: Butalbital, Aspirin, Caffeine, and Codeine Phosphate Capsules USP, 50 mg/325 mg/40 mg/30 mg.

DATE OF APPLICATION: August 29, 1996

DATE OF RECEIPT: August 30, 1996

DATE ACCEPTABLE FOR FILING: November 27, 1996

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:

Tim Ames
Project Manager
(301) 594-0305

Sincerely yours,

for 12/21/96

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

ANDA 74-951

Jerome Stevens Pharmaceuticals, Inc.
Attention: Ronald Steinlauf
Sixty DaVinci Drive
Bohemia, NY 11716

NOV 20 1996

Dear Sir:

Please refer to your abbreviated new drug application (ANDA) dated August 29, 1996, submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Butalbital, Aspirin, Caffeine, and Codeine Phosphate Capsules USP, 50 mg/325 mg/40 mg/30 mg.

We also acknowledge receipt of your correspondence dated September 30 and October 16, 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 reason:

> You have failed to provide a certification that the third (field copy) of the application has been submitted to the appropriate district office and a statement that it is a "true copy" of the technical sections contained in the application.

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

For future reference, all submissions to the ANDA must be accompanied by a cover letter and a Form FDA 356h.

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,

Jerry Phillips 11/20/96

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

Jerome Stevens Pharmaceuticals

Inc.

Generic Manufacturers

Please to File
Anne Marie H. Diebel
11/14/96

505(b)(2)(a) ok
Anne Marie H. Diebel
10/4/96

August 29, 1996

Dear Sir/Madam,

Enclosed for your review is an original ANDA for Aspirin 325mg/Butalbital 50mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP. We have enclosed fourteen (14) volumes.

Sincerely,

Ronald Steinlauf

Ronald Steinlauf
Vice President

RECEIVED

AUG 30 1996

GENERIC DRUGS

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JSP

Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

OCTOBER 16, 1996

NEW CORRESP
NC

MS. CECELIA PARISE
OFFICE OF GENERIC DRUG, CDER, FDA
DOCUMENT CONTROL ROOM
METRO PARK NORTH II
7500 STANDISH PLACE, ROOM 150
ROCKVILLE, MD 20855-2773

NAI
10/28/96
CPHS

RE: **ANDA** - 74-951

DEAR MS. PARISE:

ENCLOSED PLEASE FIND AS PER YOUR REQUEST CGMP CERTIFICATION FOR ASPIRIN 325MG/BUTALBITAL 50MG/ CAFFEINE 40MG/ CODEINE PHOSPHATE 30MG CAPSULE USP.

THANK YOU FOR YOUR ATTENTION GIVEN THIS MATTER.

SINCERELY,

Ronald Steinlauf

RONALD STEINLAUF, VICE PRESIDENT
JEROME STEVENS PHARMACEUTICALS, INC.

RECEIVED
OCT 17 1996
GENERIC DRUGS

Sixty DaVinci Drive • Bohemia, New York 11716 • Phone: (516) 567-1113 • Fax: (516) 567-1189

CGMP Certification:

The drug product, Aspirin 325mg/Butalbital 50mg/Caffeine 40mg/ Codeine Phosphate 30mg Capsule USP was manufactured by Jerome Stevens Pharmaceuticals Inc. under compliance with all current Good Manufacturing Practices listed in 21 CFR Parts 210 and 211.

Ronald Steinlauf
Vice President

October 16, 1996

505(J)(2)(a)(ok)
Ana Marie H. Waldel 12/16/96

Jerome Stevens Pharmaceuticals Inc.

Generic Manufacturers

NE

NDA ORIG AMENDMENT N/AC

NAI

Forward to C. Perise for review NC 12/4/96

12/4/96

November 26, 1996

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

RE: ANDA 74-951; Butalbital 50mg/Aspirin 325mg/Caffeine 40mg/Codeine Phosphate 30mg Capsule USP

Dear Sir/Madam,

This is a reply to your letter dated November 20, 1996. Jerome Stevens Pharmaceuticals Inc. certifies that the third (field copy) of the noted application was sent to FDA's Brooklyn, NY District Office and that it is a "true copy" of the technical sections contained in the application.

Sincerely,

Ronald Steinlauf

Ronald Steinlauf
Vice President

RECEIVED
NOV 27 ...

Nadine 12.3.96

Sixty DaVinci Drive • Bohemia, New York 11716 • Phone: (516) 567-1113 • Fax: (516) 567-1189

JSP