# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**40276**

# CORRESPONDENCE

40-276

Purepac Pharmaceutical Co.
Attention: Joan Janulis
200 Elmora Ave.
Elizabeth NJ 07207

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: Phentermine Hydrochloride Tablets USP, 37.5 mg

DATE OF APPLICATION: September 11, 1997

DATE OF RECEIPT: September 12, 1997

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:

Kassandra Sherrod
Project Manager
(301) 827-5848

Sincerely yours,

/S/

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

A Trusted Name For Over Half A Century

JREPAC

ORIGINAL

Purepac Pharmaceutical Co.
200 Elmora Avenue, Elizabeth, New Jersey 07207
908-527-9100
Fax: 908-527-0649

**UPS OVERNIGHT COURIER**

October 26, 1998

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

**FACSIMILE AMENDMENT**

**RE: ANDA #40-276, Phentermine Hydrochloride Tablets USP, 37.5 mg**

Dear Mr. Sporn:

Reference is made to our September 11, 1997 submission of an Abbreviated New Drug Application for Phentermine Hydrochloride Tablets USP, 37.5 mg, ANDA #40-276. Further reference is made to your Facsimile Minor Chemistry deficiency letter dated October 16, 1998, and a telephone conversation which took place on October 21, 1998, between Dr. Karen Bernard and Ms. Kassandra Sherrod of OGD and Janak Jadeja of Purepac. Your comments are provided in bold type, followed by our response.



**Chemistry Deficiencies**

Redacted 1

pages of trade

secret and/or

confidential

commercial

information

This concludes our Facsimile Amendment in response to your letter dated October 16, 1998. If you have any questions regarding this submission, please do not hesitate to call the undersigned at (908) 659-2430.

Sincerely,

**PUREPAC PHARMACEUTICAL CO.**

Joan Janulis, R.A.C.
Vice President, Regulatory Affairs

Enclosures

A Trusted Name For Over Half A Century

PUREPAC

ORIGINAL

Purepac Pharmaceutical Co.
200 Elmora Avenue, Elizabeth, New Jersey 07207
908-527-9100
Fax: 908-527-0649

**UPS OVERNIGHT COURIER**

ORIG AMENDMENT
N/AM

**MINOR AMENDMENT**

August 20, 1998

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

**RE: ANDA #40-276, Phentermine Hydrochloride Tablets USP, 37.5 mg**

Dear Mr. Sporn:

Reference is made to our September 11, 1997 submission of an Abbreviated New Drug Application and subsequent amendment dated February 13, 1998 for Phentermine Hydrochloride Tablets USP, 37.5 mg, ANDA #40-276. Further reference is made to your Minor Chemistry deficiency letter dated July 21, 1998. Your comments are provided in bold type, followed by our response.

**A. Chemistry Deficiencies**

AUG 21 1998



GENERIC DRUGS

Redacted 2

pages of trade secret and/or confidential commercial information

In conjunction with this submission, Purepac is providing a copy of this amendment to our local district office. The required Field Copy Certification is included in Section 5.

This concludes our Minor Amendment in response to your letter of July 21, 1998. If you have any questions regarding this submission, please do not hesitate to call me at (908) 659-2430.

Sincerely,

**PUREPAC PHARMACEUTICAL CO.**

Joan Janulis, R.A.C.
Vice President, Regulatory Affairs

JJ:ch
Enclosures

A Trusted Name For Over Half A Century

PUREPAC

ORIGINAL

Purepac Pharmaceutical Co.
200 Elmora Avenue, Elizabeth, New Jersey 07207
908-527-9100
Fax: 908-527-0649

**UPS OVERNIGHT COURIER**

Labeling

**MAJOR AMENDMENT**

February 13 , 1998

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

ORIG AMENDMENT

APC

**RE: ANDA #40-276, Phentermine Hydrochloride Tablets USP, 37.5 mg**

Dear Mr. Sporn:

Reference is made to our September 11, 1997 submission of an Abbreviated New Drug Application for Phentermine Hydrochloride Tablets USP, 37.5 mg, ANDA #40-276. Further reference is made to your Major Chemistry deficiency letter dated January 27, 1998. Your comments are provided in bold type, followed by our response.

**A. Chemistry Deficiencies**

FEB 17 1998

GENERIC DRUGS

Redacted 5

pages of trade

secret and/or

confidential

commercial

information

**B. Labeling Deficiencies**

**1. CONTAINER 100s and 500s**

**Satisfactory in draft**

Purepac's Response

No response is required.

**2. INSERT (*specific comments are not provided in this letter*)**

**Please revise package insert labeling, as instructed above, and submit final printed container labels and draft insert labeling or final print if you prefer.**

**Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.**

**To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with the enclosed labeling with all differences annotated and explained.**

Purepac's Response

Section 4 of this amendment contains twelve (12) final printed labels for each package size and twelve (12) final printed inserts, incorporating the requested revisions. In addition, Section 5 contains the side-by-side comparisons with all differences annotated and explained.

In conjunction with this submission, Purepac is providing a copy of the amendment to our local district office. The required Field Copy Certification is included in Section 6.

This concludes our Major Amendment in response to your letter of January 27, 1998. If you have any questions regarding this submission, please do not hesitate to call me at (908) 659-2430.

Sincerely,

**PUREPAC PHARMACEUTICAL CO.**

Elizabeth Trowbridge /for

Joan Janulis, R.A.C.
Vice President, Regulatory Affairs

JJ:ch
Enclosures