

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 74936

ADMINISTRATIVE DOCUMENTS

APPROVAL PACKAGE SUMMARY

ANDA #: 74-936

FIRM: Purepac DRUG: Naproxen

DOSAGE: Delayed-Release Tablets STRENGTH: 375 mg and 500 mg

cGMP STATEMENT/EIR UPDATE STATUS:

cGMP: Satisfactory (page # 2823)

EER: Acceptable dated 16-APR-1997

Bio STUDY(ies)/BIOEQUIVALENCE STATUS: O.K. LETTER SENT 1/15/97

METHODS VALIDATION(Including dosage form description):

DS is compendial. Method validation for the drug product is pending.

STABILITY(Conditions, Containers, methods):

Bio batch?

SPECIFICATIONS

Test	Method	Specification
Description	visual	Yellow, capsule shaped, enteric coated tablet, printed (black) with Purepac logo
Drug Release	USP 23 <724>, App 2, 50 rpm;	
Physical evaluation organoleptic, e.g. smear ink		
Assay		
Related Compounds		
Moisture	USP 23 <921> method 1a	

Stability batches are the same as the bio batches.

Stability container/closures are the same as those described in the container section.

LABELING REVIEW STATUS:satisfactory per review by C. Park dated September 29, 1997.

STERILIZATION VALIDATION(If Applicable): N/A

RECORD OF TELEPHONE CONVERSATION

DATE: February 23, 1998

PRODUCT NAME: Naproxen Sodium 375 mg & 500 mg

ANDA/AADA NUMBER: 74-936

FIRM NAME: Purepac Pharmaceuticals

NAME AND TITLE OF PERSON WITH
WHOM CONVERSATION WAS HELD:

Nick Falcone & Evette, Philadelphia District Laboratory

PARTICIPANT(S) TELEPHONE:

Mr. James Wilson III, Branch I Project Manager, OGD, CDER, FDA

MINUTES OF CONVERSATION:

Evette indicated that Nick Falcone had just assigned Purepac's Naproxen Sodium Methods Validation on February 20, 1998. It should take 2 ½ weeks to finish.

NAME OF OGD REPRESENTATIVE:

James W. Wilson III, Project Manager, Branch I OGD, CDER, FDA

SIGNATURE OF OGD REPRESENTATIVE:

J. W. Wilson III

(U)
DIVISION/BRANCH: Office of Generic Drugs
Division I, Branch 1.

MINUTES PREPARED BY:

Jim Wilson III, Project Manager, Branch I, OGD, CDER, FDA

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 74936

CORRESPONDENCE

A Trusted Name For Over Half A Century



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

9/12/96
file Chen

UPS OVERNIGHT COURIER

July 31, 1996

RECEIVED

AUG 1 1996

GENERIC DRUGS

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

RE: Abbreviated New Drug Application for Naproxen Delayed-Release Tablets, 375 mg and 500 mg

Dear Mr. Sporn:

In accordance with the regulations promulgated under Section 505 of the Federal Drug and Cosmetic Act as amended, Purepac Pharmaceutical Co. is submitting this Abbreviated New Drug Application (Archival and Review Copy) for Naproxen Delayed-Release Tablets, 375 mg and 500 mg.

This Abbreviated New Drug Application has been prepared in accordance with Policy and Procedure Guide #30-91, dated April 10, 1991, and contains a total of twenty-one (21) volumes comprising the Archival Copy and the Review Copy (chemistry, manufacturing and controls review part and bioavailability/ bioequivalence review part).

In conjunction with this submission, Purepac has provided a Field Copy of this application to our local district office in accordance with 21CFR 314.94. Please note that the required Field Copy Certification is contained in Section XXI of our abbreviated application.

In addition, a certification in accordance with Section 306(K) of the Federal Food Drug and Cosmetic Act as amended by the "Generic Drug Enforcement Act" is contained in Section IX of this application. Three (3) separately bound copies of analytical methods and related descriptive information are also included.

**RE: Abbreviated New Drug Application for Naproxen Delayed-Release
Tablets, 375 mg and 500 mg**

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In support of this application, Purepac has manufactured Naproxen Delayed-Release Tablets, 375 mg, Test Batch #PI-917 and Naproxen Delayed-Release Tablets, 500 mg, Test Batch #PI-919. These batches were manufactured and packaged in compliance with Policy and Procedure Guide #41-95 entitled "Guidance on the Packaging of Test Batches" and specifically meet the criteria established under Section 3.E.2 of this guide for partial packaging. Full documentation supporting Test Batches #PI-917 and #PI-919 are included in Section XII of this application.

Purepac Pharmaceutical Co. trusts that you will find this application complete and well organized, and looks forward to the review process.

Sincerely,

PUREPAC PHARMACEUTICAL CO.



Helena Goncalves, RPh
Associate, Regulatory Affairs

HG:cch
Enclosures

97

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

MINOR AMENDMENT

ORIG AMENDMENT
N/A/M

UPS OVERNIGHT COURIER

December 4, 1997

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

RE: ANDA #74-936, Naproxen Delayed-Release Tablets, 375 mg and 500 mg

Dear Mr. Sporn:

Reference is made to our July 31, 1996 submission of an Abbreviated New Drug Application for Naproxen Delayed-Release Tablets, 375 mg and 500 mg, ANDA #74-936. Further reference is made to your Minor Chemistry deficiency letter dated November 19, 1997. Your comments are provided in bold type, followed by our response.

A. Deficiencies

RECEIVED

GENERIC DRUGS

Handwritten:
12-9-97

MINOR AMENDMENT

**RE: Naproxen Delayed-Release Tablets, 375 mg and 500 mg.
ANDA #74-936**

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Agency's Comments

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

Since this drug product is not covered by an official monograph in the USP, the analytical methods must be validated by an FDA field laboratory. The methods evaluation report from the District Office is yet pending.

Purepac's Response

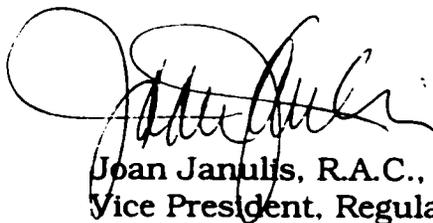
Purepac acknowledges this requirement. Please be advised that samples and related information were submitted to the FDA laboratory on September 19, 1997.

This concludes our **MINOR AMENDMENT** in response to your letter of November 19, 1997. Please note that Purepac has submitted a complete copy of this amendment to our field office in accordance with 21 CFR 314.60(c). The required certification is contained in this submission.

Purepac Pharmaceutical Co. trusts that you will find this amendment complete and in order, and looks forward to the approval of the Abbreviated New Drug Application.

Sincerely,

PUREPAC PHARMACEUTICAL CO.



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

JJ:cch
Enclosures