

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S003**

**Name:** Sodium Nitroprusside Injection

**Sponsor:** Hospira

**Approval Date:** February 24, 1994

**Indication:** Immediate reduction of blood pressure of patients in hypertensive crises.

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S003**  
**CONTENTS**

<b>Reviews / Information Included in this Review</b>
--

<b>Approval Letter</b>	<b>X</b>
<b>Tentative Approval Letter</b>	
<b>Labeling</b>	
<b>Labeling Review(s)</b>	
<b>Medical Review(s)</b>	
<b>Chemistry Review(s)</b>	<b>X</b>
<b>Pharm/Tox Review</b>	
<b>Bioequivalence Review(s)</b>	
<b>Statistical Review(s)</b>	
<b>Microbiology Review(s)</b>	
<b>Other Review(s)</b>	
<b>Administrative &amp; Correspondence Documents</b>	

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S003**

**APPROVAL LETTER**

ANDA 71-961/S-003 (Nitropress® Sodium Nitroprusside Injection,  
50 mg)  
70-566/S-010 (Nitropress® Sterile Sodium Nitroprusside,  
50 mg)

Abbott Laboratories  
Attention: Frederick Gustafson  
One Abbott Park Road  
Abbott Park, Illinois 60064-3500

FEB 24 1994

Dear Sir:

This is in reference to your supplemental new drug applications dated July 28, 1993 submitted pursuant to 21 CFR 314.70, regarding your abbreviated new drug applications for Sterile Sodium Nitroprusside USP, 50 mg.

The supplemental applications provide for [REDACTED] (b) (4)

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

*Frank O. Holcomb 2/22/94*

Rashmikant M. Patel, Ph.D.  
Director  
Division of Chemistry I  
Office of Generic Drugs  
Center for Drug Evaluation and Research

cc: ANDA 71-961/S-003, 70-566/S-010  
Division File  
FIELD COPY  
HFD-600/Reading File  
HFD-82

Endorsements:

HFD-623/EMurphy/2/9/94 *E. Murphy 2/22/94*  
HFD-623/JFan for RKishore/2/10/94 *J. Fan for Dr. Kishore 2/22/94*  
HFD-623/JWilson/2/15/94 *J. Wilson 2/29/94*  
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F/T by gp/2/22/94  
APPROVAL

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S003**

**CHEMISTRY REVIEWS**

Chemistry, Manufacturing and Control Supplemental Review of  
Sodium Nitroprusside

ANDA 71-961/S-003 (50 mg, Fliptop vial)  
70-566/S-010 (50 mg, ADD-Vantage)

NAME AND ADDRESS OF APPLICANT:

Abbott Laboratories  
Attention: Frederick Gustafson  
One Abbott Park, Illinois

PURPOSE OF AMENDMENT/SUPPLEMENT

The purpose of ANDA's 71-961/S-003 and 70-566/S-010 provides for

(b) (4)

DATE(S) OF SUBMISSION(S)

71-961/S-003 July 28, 1993  
70-566/S-010 July 28, 1993

PHARMACOLOGICAL CATEGORY

Hypotensive Agent

TRADE NAME

Nitopress Injection (71-961)  
Nitopress ADD-Vantage (70-566)

NONPROPRIETARY NAME

Sterile Sodium Nitroprusside

DOSAGE FORM

Fliptop vial (I.V)  
ADD-Vantage Vial

POTENCY

50 mg  
50 mg

RX OR OTC

R<sub>x</sub>

REMARKS AND CONCLUSION

Approval - Supplement

Reviewer

Elise Murphy

Date Completed

February 9, 1994

cc: ANDA 71-961  
Division File  
FIELD COPY

Endorsements:

HFD-623/EMurphy/2/9/94 *E. Murphy 2/22/94*  
HFD-623/JFan for RKishore/2/9/94 *JFan for Dr. Kishore 2/22/94*  
F/T by cls/02/17/94

RELATED IND/NDA/DMF

No DMF's cited for this review.

(b) (4)

ORDER OF REVIEW:

The application submissions covered by this review were taken in  
the date order of receipt                      Yes   X