

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S004**

**Name:** Sodium Nitroprusside Injection

**Sponsor:** Hospira

**Approval Date:** November 15, 1994

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

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S004**  
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**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S004**

**APPROVAL LETTER**

ANDA 70-566/S-011 (ADD-Vantage vial)  
71-961/S-004 (Fliptop vial)

FEB 10 1995

Abbott Laboratories  
Hospital Products Division  
Attention: Frederick Gustafson  
One Abbott Park Road D-389, AP-30  
Abbott Park, Illinois 60064-3500

Dear Sir:

This is reference to your supplemental new drug applications dated May 6, 1994 submitted pursuant to 21 CFR 314.70 (c)(1) regarding your abbreviated new drug applications for Nitropress® Injection (Sodium Nitroprusside Injection, 50 mg/2 mL vial).

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 approved abbreviated new drug application in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

*R. K. Kulkarni*  
2-9-95

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

cc: ANDA 70-566  
71-961  
Division File (2x)  
Field Copy  
HFD-600/Reading File  
HFD-82

Endorsements:

HFD-620/K.Muhvich/2-9-95 *2/9/95 KH Muhvich*  
HFD-623/R.Kishore/1/31/95, 2-2-95 *2-2-95 R.Kishore*  
HFD-617/J.Wilson/1/31/95, 2-2-95 *2/9/95 J.Wilson*  
X:\WPFILE\MICROREV\71-961.195  
F/T by dvw 2-8-95

APPROVAL

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA 71-961Orig1/S004**

**MICROBIOLOGY REVIEW**

DIVISION OF CHEMISTRY I  
OFFICE OF GENERIC DRUGS

Microbiologist's Review #1

November 15, 1994

A. 1. ANDA: 71-961/S-004

APPLICANT: Abbott Laboratories  
Hospital Products Division  
One Abbott Park Road  
Abbott Park, Illinois 60064-3500

2. PRODUCT NAMES: Nitropress® Injection  
(Sterile Sodium Nitroprusside)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

50 mg/2 mL contained in a Fliptop vial for intravenous infusion

4. METHOD(S) OF STERILIZATION:

(b) (4)

5. PRINCIPLE INDICATIONS: Immediate reduction of blood pressure of patients in hypertensive crisis

6. PHARMACOLOGICAL CATEGORY: Hypotensive agent

B. 1. DATE OF INITIAL SUBMISSION:

May 6, 1994 (Received by OGD on May 12, 1994)  
- Subject of this Review

2. DATE OF AMENDMENT: N/A

3. ASSIGNED FOR REVIEW: November 8, 1994

(b) (4)

(b) (4)

D. CONCLUSIONS: The submission is therefore recommended for approval on the basis of (b) (4). Specific comments are provided in "E. Review Notes".

*Kenneth H. Muhvich 11/15/94*

Kenneth H. Muhvich, Ph.D.

cc:

Original ANDA **71-961/S-004**

HFD-615/CSO/WRickman

HFD-620/DirectorDivChemistryI/RPatel

drafted by: KHMuhvich, 11/15/94

R/D initialed by FHolcombe

*received  
11/16/94*