

018-998-ORIG APPROVAL-PKG

# CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998

## CONTENTS

**VASOTEC**

### Reviews / Information Included in this NDA Review.

Approval Letter	
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	X
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	X
Statistical Review(s)	X
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	X
Administrative Document(s)	X
Correspondence	