

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

62483

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT		NDA NUMBER <div style="font-size: 1.2em; font-family: cursive;">62-483</div>
		DATE APPROVAL LETTER ISSUED
TO: Press Relations Staff (HF1-40)	FROM: <input checked="" type="checkbox"/> Bureau of Drugs <input type="checkbox"/> Bureau of Veterinary Medicine	
ATTENTION Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.		
TYPE OF APPLICATION <input checked="" type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO NDA <input type="checkbox"/> ABBREVIATED ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO ANDA		CATEGORY <input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG <div style="font-size: 1.2em; font-family: cursive;">Grifulvin V (griseofulvin microsize)</div>		
DOSAGE FORM <div style="font-size: 1.2em; font-family: cursive;">Suspension</div>	HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	
ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.) <div style="font-size: 1.2em; font-family: cursive;">griseofulvin microsize 125 mg / ⁵/₁ ml</div>		
NAME OF APPLICANT (Include City and State) <div style="font-size: 1.2em; font-family: cursive;">Ortho Pharmaceutical Corporation Raritan, N. J. 08869</div>		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY <div style="font-size: 1.2em; font-family: cursive;">Anti-fungal agent</div>		
COMPLETE FOR VETERINARY ONLY		
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLETE FOR SUPPLEMENT ONLY		
CHANGE APPROVED TO PROVIDE FOR		
FORM PREPARED BY		
NAME <div style="font-size: 1.5em; font-family: cursive;">/S/</div>	DATE <div style="font-size: 1.2em; font-family: cursive;">1/19/84</div>	
FORM APPROVED BY		
NAME <div style="font-size: 1.5em; font-family: cursive;">/S/</div>	DATE <div style="font-size: 1.2em; font-family: cursive;">1/26/84</div>	<div style="font-size: 1.2em; font-family: cursive;">O. W. D.</div>