

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
62483

CORRESPONDENCE

Our reference: 62-483

Ortho Pharmaceutical Corporation
Attention: A. J. Vazakas, Ph.D.
Manager of Regulatory Affairs
Raritan, New Jersey 08869

January 4, 1984

Gentlemen:

Please refer to your Antibiotic Form 5 application for Grifulvin V (griseofulvin microsize) Suspension, 125 mg/ml, and to your amendment dated December 8, 1983.

We have completed our review of the amendment and it is not approvable at this time due to the following deficiencies:

1. The submission does not contain adequate stability data as requested in our letter dated November 17, 1983.
2. The submission does not contain adequate exhibit samples as requested in our letter dated November 17, 1983.

Please submit the requested information promptly.

Sincerely yours,

John M. Singer
Antibiotic Drug Review Branch (HFN-535)
Division of Generic Drugs

HFN-535
HFN-535/0D
R/D JMSinger 12/29/83
HFN-530 (Dr. Seife)