

62483/S11

AADA: 62-483/S-011

The R.W. Johnson Pharmaceutical
Research Institute
Division of Ortho Pharmaceutical Corporation
Attention: Thomas P. Koestler, Ph.D.
Route 202 South, P.O. Box 300
Raritan, New Jersey 08869-0602

APR 13 1993

Dear Sir:

Reference is made to your supplemental antibiotic drug application dated February 5, 1993, submitted pursuant to Section 314.70 of the Regulations, regarding your abbreviated antibiotic application for Grifulvin V® (Griseofulvin Oral Suspension) Microsize, 125 mg/5 mL.

The supplemental application provides for revised "booklet" package insert labeling and container labels (120 mL) and reflecting changes to the product name and other minor changes.

We have completed the review of this supplemental application and it is approved. Our letter of January 26, 1984, detailed the conditions relating to the approval of this abbreviated application.

The material submitted is being retained in our files.

Sincerely yours,

/S/

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

/R

4-13-93

cc: AADA 62-483
Dup Division File *Shannon April 20 1993*
HFD-638/CShannon/JPhillips(no cc:)
HFD-600/RF
HFC-130/JAllen *Phillips 4/13/93*
HFD-82

Approval

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mpd/4/8/93/62483S.011
Approval

CShannon 4-12-93

JPhillips 4/13/93