62483/512

AADA 62-483/S-012

The R.W. Johnson Pharmaceutical Research Institute
Attention: Stephenie Barba
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

NOV 22 1995

Dear Madam:

This is in reference to your supplemental antibiotic drug application dated September 11, 1995, submitted pursuant to 21 CFR 314.70, regarding your abbreviated antibiotic application for GRIFULVIN V^{R} (griseofulvin oral suspension) microsize.

The supplemental application provides for the following contract laboratory to conduct chemical assays for release and stability:

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated antibiotic application described in 21 CFR 314.81.

The material submitted is being retained in our files.

Sincerely yours,

/S/ 11/22/95

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

1. CHEMISTRY REVIEW NO. 1

2. AADA # 62-483/S-012

3. NAME AND ADDRESS OF APPLICANT

The R.W. Johnson Pharmaceutical Research Institute
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

4. BASIS OF SUBMISSION
USP 23

5. SUPPLEMENT(s)
S-012

6. PROPRIETARY NAME
GRIFULVIN V® Suspension

7. NONPROPRIETARY NAME
griseofulvin oral suspension

8. SUPPLEMENT(s) PROVIDE(s) FOR:

The supplement provides for the following contract laboratory to conduct chemical assays for release and stability:

9. AMENDMENTS AND OTHER DATES:
N/A

10. PHARMACOLOGICAL CATEGORY
Antifungal antibiotic

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
N/A

13. DOSAGE FORM
Oral Suspension

14. POTENCY
125 mg/mL

15. CHEMICAL NAME AND STRUCTURE
$C_{17}H_{17}ClO_6$ 352.77

16. RECORDS AND REPORTS
N/A

17. COMMENTS
N/A

18. CONCLUSIONS AND RECOMMENDATIONS
The supplement may be approved with an acceptable EER for

19. REVIEWER:
V.Walton

DATE COMPLETED:
11/6/95

Redacted 3

pages of trade

secret and/or

confidential

commercial

information

Chem Review #1

NDA NO _____ REF. NO 5C012
NDA SUPPL FOR Control #cw

THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

SEP 11 1995

Noted
Review in turn
Mark Anderson
4/21/95

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

SUPPLEMENTAL APPLICATION
21 CFR 314.70(b)

AADA 62-483
GRIFULVIN V® (griseofulvin oral suspension) microsize

Dear Sir/Madam:

Reference is made to our approved Abbreviated Antibiotic Drug Application 62-483. Pursuant to 21 CFR §314.70(b) we wish to provide for the following contract laboratory to conduct chemical assays for release and stability:

In accordance with 21 CFR 314.71(b) we are providing a field copy to the FDA Newark District Office. We certify that this field copy is a true copy of the archival and review copies submitted to AADA 62-483.

Should you have any questions and/or comments, please contact me directly at (908) 704-4775 or our new phone number dedicated for FDA use at (908) 704-4600.

Very truly yours,

Michael N Kaufman for
Stephenie Barba
Director
Regulatory Affairs

RECEIVED
SEP 12 1995
GENERIC DRUGS

n:\walker\specta\lab

Withdrawn
4-16-97