62483/58

AADA 62-483/S-008

28 MAR 1990

The R.W. Johnson
Pharmaceutical Research Institute
Attention: Ms. Vivian Chester
Route 202, P.O. Box 300
Raritan, NJ 08868-0602

Dear Madam:

Reference is made to your supplemental antibiotic drug application submitted pursuant to Section 314.70 of the Regulations, dated January 26, 1990, regarding your abbreviated antibiotic drug application for GRIFULVIN V Suspension.

The supplemental application provides for the replacement of the
assay procedure by a
as specified in the current edition of the USP (XXII).

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 as part of your application.

Sincerely yours,

/S/ for 3/22/90

Acting Director
Division of Generic Drugs
Center for Drug Evaluation and Research

cc:
HFD-235
HFD-235/RF
JHarrison/VWalton
mw 3/22/90
6807d

V.W. 3/22/90

3/22/90

1. CHEMIST'S REVIEW NO. 1

2. AADA # 62-483/S-008

3. NAME AND ADDRESS OF APPLICANT

The R.W. Johnson
Pharmaceutical Research Institute
Route 202
Raritan, NJ 08869-0602

5. SUPPLEMENT(s)

S-008

6. TRADE NAME

GRIFULVIN V Suspension

7. NONPROPRIETARY NAME

Griseofulvin

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

the addition of the compendial assay procedure for giseofulvin as an analytical method.

10. PHARMACOLOGICAL CATEGORY

Antibiotic

11. Rx or OTC

Rx

13. DOSAGE FORM

Oral suspension

14. POTENCY

125 mg/5cc

18. CONCLUSIONS AND RECOMMENDATIONS

The supplement may be approved.

19. REVIEWER:

Vernon Walton

DATE COMPLETED:

3/21/90

/S/ 3/22/90

/S/ 3/22/90

Redacted 1

pages of trade

secret and/or

confidential

commercial

information

Chemistry

62-483

THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE
ROUTE 202, P O BOX 300, RARITAN, NEW JERSEY 08869-0602

JAN 26 1990

Special Supplement
Changes Being Effected
21 CFR 314.70(c)

Division of Generic Drugs
Attn: DOCUMENT CONTROL ROOM
HFD #230, Room 17B-20
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857-1706

[redacted] GRIFULVIN V® Suspension

Please Cross-Refer to:
NDA 50-448
GRIFULVIN V® Suspension

Dear Sir/Madam:

Reference is made to our approved New Drug Application 62-483 for GRIFULVIN V® (griseofulvin microsize) Suspension, 125 mg/5 mL. At this time we wish to notify you that we have added the assay procedure for griseofulvin as an analytical method. The method is in addition to the presently approved assay procedure contained in the NDA. This additional assay method is specified in the current USP monographs for the bulk drug substance, griseofulvin, and the finished suspension product, griseofulvin oral suspension. Although in accordance with the regulations, such an addition may be submitted in the Annual Report for this NDA, we are providing for it at this time because the assay will replace the assay as our primary regulatory procedure for the release of bulk drug substance and finished oral suspension. The procedure will be maintained as an alternate procedure.

Appended herewith is an updated section 4(a) "Details of analytical procedures for all active ingredients...". The updated section 4(a) now provides for the method as well as the procedure.

Should you have any questions, please contact me directly at (201) 704-4530.

RECEIVED
FEB 2 1990

Sincerely yours,

The R.W. Johnson Pharmaceutical
Research Institute

Vivian A. Chester

Vivian Chester
Director
Regulatory Affairs

3440/5
attachment