62483/59

AADA 62-483/S-009

The R. W. Johnson
Pharmaceutical Research Institute
Attn.: Thomas P. Koestler, Reg. Affairs
Route 202 South, P.O.Box 300
Raritan, NJ 08869-0602

SEP 17 1991

Dear Sir:

Reference is made to your supplemental antibiotic drug application submitted pursuant to Section 314.70 of the Regulations, dated August 20, 1990, regarding your abbreviated antibiotic application for GRIFULVIN V (griseofulvin microsize) Suspension, 125 mg/5 mL.

The supplemental application provides for a revision in the label claim for alcohol content from [redacted].

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/ 9/14/91

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

cc: AADA# 62-483/S-009
DUP/Division File
HFD-600/RF
HFC-130/JAllen
HFD-635/RF
HFD-635/JHarrison/VWalton/date V.W. 9/11/91
HFD-635/JHannan JHannan 9/12/91
R/D initialed by JHarrison JHarrison 9/11/91

APPROVAL SUPPLEMENT

AADA
62-483/S-009
Chemist's review # 1.

NAME AND ADDRESS OF APPLICANT:
The R.W.Johnson
Pharmaceutical Research Institute
Route 202 South, P.O.Box 300
Raritan, N.J. 08869-0602

PURPOSE OF AMENDMENT/SUPPLEMENT
This supplement provides for a revision in the label claim for alcohol content from % .

DATE(S) OF SUBMISSION(S)
August 20, 1990

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
Antibiotic	GRIFULVIN V	Griseofulvin

DOSAGE FORM	POTENCY	RX OR OTC
Oral Suspension	125 mg/5 mL	Rx

SAMPLES	RELATED IND/NDA/DMF	STERILIZATION
n/a	n/a	n/a

LABELING
Package insert and container labels revised to indicate that product contains % alcohol.

BIOEQUIVALENCY STATUS
n/a

ESTABLISHMENT INSPECTION
n/a

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS
This supplement provides for a revision in the label claim for alcohol content from % to more accurately reflect total alcohol content of the product, which consists of Alcohol, USP added during the manufacture and that contributed by excipients Flavor. The previous declaration of % only reflected alcohol added during manufacture of the suspension.

Applicant added a new finished product specification, "Alcohol Content - Not more than %" and a validated assay procedure for the determination of in the suspension.

Applicant states the following: "the total contribution of alcohol in this product is derived from the following three sources:

1. Alcohol, USP added during the manufacturing process % by volume).
2. flavor (% by volume).
3. Flavor (% by volume).

When the three exicipients are combined, the total amount of by volume in the final formulation ranges from %.
Revised labeling will be submitted in the next annual report.

Review of annual report dated 3-28-91

Examination of the labeling in the most recent annual report show the package insert and container labels have been revised to indicate that product contains % alcohol.

PACKAGING
n/a

STABILITY
n/a

REMARKS AND CONCLUSION
The supplement may be approved.

RECALLS	Reviewer		Date Completed
n/a	V.Walton	V.W. 9/11/91	9/10/91

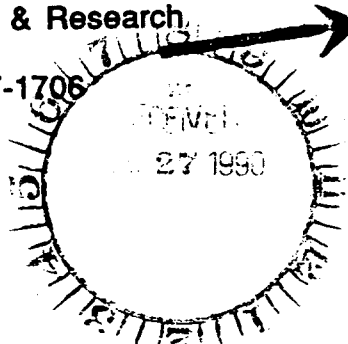
cc: AADA # 62-483/S-009
Review Chemist's name V.Walton
Supervisor's name J.Harrison

/S/

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

AUG 20 1990

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



Special Supplement
Changes Being Effected
21 CFR 314.70(c)

NDA 62-483
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 are revising our label claim for alcohol content in GRIFULVIN V Suspension from % to more clearly reflect total alcohol content of this product, which consists of Alcohol, USP added during the manufacture and that contributed by the excipients Cocoanut Custard Flavor and Orange Extract ES Flavor. The previous declaration of % only reflected alcohol added during manufacture of GRIFULVIN V Suspension. Accordingly, we wish to notify you that we have added a new finished product specification, "Alcohol Content - Not more than %" and a validated assay procedure for analysis of ethanol in GRIFULVIN V Suspension. We plan to implement the analysis of ethanol in GRIFULVIN V Suspension immediately following submission of this supplement.

As noted above, the total contribution of alcohol in this product is derived from three sources, Alcohol, USP % by volume), Flavor (% by volume) and Flavor % by volume). We expect the exact percentages for the flavorants to vary slightly depending on the lot received, but to fall approximately within these designated ranges. When these three excipients are combined, the total amount of ethanol by volume in the final formulation ranges from %. Thus, the alcohol content specification of "Not more than %" reflects the highest percentage of alcohol expected to be in this product.

For your information, the labeling components reflecting this revision will be submitted in the respective Annual Reports for GRIFULVIN V Tablets, NDA 62-279 and GRIFULVIN V Suspension, NDA 62-483.

ORIGINAL

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Appended herewith is an updated section II.F. (formerly section 4(b)) "Specifications and Analytical Methods for the Drug Product". The updated section II.F. now provides for the current FDA-approved finished product specifications, the new finished product specification for Alcohol Content and the procedure for analysis of ethanol in GRIFULVIN V Suspension.

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

Sincerely yours,

The R.W. Johnson
Pharmaceutical Research Institute

Vivian A. Chester

Vivian A. Chester
Director
Regulatory Affairs

VAC/dd
Grifulvin\NDA