62483/S14

ANDA 62-483/S-014

Johnson & Johnson
Consumer Companies, Inc.
Attention: Lewis Gryziewicz
199 Grandview Road
Skillman, NJ 08558

SEP 21 1998

Dear Sir:

This is in reference to your supplemental new drug application dated April 8, 1998, submitted pursuant to 21 CFR 314.70(c), regarding your abbreviated new drug application for GRIFULVIN® (griseofulvin oral suspension) microsize.

The supplemental application provides for the following additional 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 new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

/S/ 9/18/98

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

Office of Generic Drugs
Supplement Review

ANDA 62-483/S-014

NAME AND ADDRESS OF APPLICANT

Johnson & Johnson
Consumer Companies, Inc.
199 Grandview Road
Skillman, NJ 08558

PURPOSE OF SUPPLEMENT

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

DATE OF SUBMISSION
April 8, 1998

PHARMACOLOGICAL CATEGORY
Antifungal

TRADE NAME
GRIFULVIN V® Suspension

NONPROPRIETARY NAME
Griseofulvin Oral Suspension

DOSAGE FORM
Oral Suspension

STRENGTHS
125 mg/5mL

RX OR OTC
Rx

SAMPLES
N/A

RELATED IND/NDA/DMF
N/A

STERILIZATION
N/A

LABELING
N/A

BIOEQUIVALENCY STATUS
N/A

ESTABLISHMENT INSPECTION

EER requested for:

EER ACCEPTABLE June 26, 1998

COMPONENTS/COMPOSITION/MANUFACTURING/CONTROLS

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

Included in the supplement is certification from the testing laboratory stating they are in conformance with current Good Manufacturing Practices.

PACKAGING
N/A

STABILITY
N/A

REMARKS AND CONCLUSION
The supplement is approvable with the acceptable EER dated June 26, 1998 for

RECALLS
N/A

REVIEWER
V.Walton

DATE COMPLETED
9/9/98

APPEARS THIS WAY
ON ORIGINAL

AAI®

Laboratory:
6101 Quadrangle Drive
Chapel Hill, NC 27514
919.493.5718
Telefax: 919.493.9404

Corporate and Laboratory:
1206 North 23rd Street
Wilmington, NC 28405
910.763.4536
Telefax: 910.251.6755

Statement of Good Manufacturing Practices

"AAI is registered with the Food and Drug Administration, registration number 10-49418. We operate our laboratory in compliance with Good Manufacturing Practices and maintain all our records as confidential and the property of the contracting firm."

Reported By:

Girish G. Patel, B.S.
Laboratory Supervisor

Good Manufacturing Practices Reviewed By:

Patricia C. Berkowitz, B.S.

Approved By:

3/13/98

Keith Whitehead, Ph.D.
Laboratory Director