62483/S15

ANDA 62-483/S-015

DEC 30 1998

Johnson & Johnson Consumer Companies, Inc.
Attention: Lewis Gryziewicz
199 Grandview Road
Skillman, NJ 08858

Dear Sir:

This is in reference to your supplemental drug application dated June 29, 1998, submitted pursuant to 21 CFR 314.70), regarding your abbreviated new drug application for GRIFULVIN® (griseofulvin oral suspension) microsize, 125 mg/5 mL.

The supplemental application provides for a change in the resin used for the cap.

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/

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

Office of Generic Drugs
Supplement Review

CHEMIST'S REVIEW # 1

ANDA 62-483/S-015

NAME AND ADDRESS OF APPLICANT

Johnson & Johnson Consumer Companies, Inc.
199 Grandview Road
Skillman, NJ 08858

PURPOSE OF SUPPLEMENT
The supplemental application provides for a change in the resin used for the cap.

DATE OF SUBMISSION
June 29, 1998

PHARMACOLOGICAL CATEGORY
Antifungal

TRADE NAME
GRIFULVIN V^{R} Suspension

NONPROPRIETARY NAME
Griseofulvin

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
N/A

COMPONENTS/COMPOSITION/MANUFACTURING/CONTROLS
N/A

PACKAGING - Satisfactory

The supplemental application provides for a change in the resin used for the cap.

is currently used to mold the Clic-Loc Child Resistant Closures. This resin will be replaced by

Authorization letter submitted for DMF

Clic-Loc Child Resistant Closures
Note: DMF was reviewed by J. Smith on 5/15/96 and found to be satisfactory for Clic-Loc Child Resistant Closures.

Authorization letter submitted for DMF
for Resin
Note: DMF was reviewed by A. Mueller on 12/12/94 and found to be satisfactory.

Authorization letter submitted for DMF (Packaging Materials) on

is using to mold their Clic-Loc Child Resistant Closures which are supplied to Johnson & Johnson Consumer Companies, Inc. to be used for packaging requiring the to conform with FDA regulation 21 CFR 177.1520. certifies that their resin meets all requirements for food contact uses pursuant to 21 CFR 177.1520(c)(1.1) and all other applicable FDA regulations covering adjutants used in this product's formulation.

Stability Data

In support of this change the firm submitted three months of stability data on GRIFULVIN V Suspension packaged with the new cap, upright and inverted, at 25°C/60%RH and 40°C. Data are also provided on the same lot of product packaged using the current

approved cap.

Reviewer's comments

All stability data are satisfactory
The stability of the product with the new cap is equivalent to the stability in the current package. Firm pledges to continue to monitor this batch until its expiration date and report the data in the annual report. The following tests are performed on stability samples: Griseofulvin Assay, Methyl paraben, Propyl paraben, Alcohol Content, pH, Deliverable Volume, Particle Size, and Chromatographic Purity.

STABILITY
See above

REMARKS AND CONCLUSION
The supplement is approvable.

RECALLS
N/A

REVIEWER
V.Walton

DATE COMPLETED
12/30/98

Johnson & Johnson
CONSUMER COMPANIES, INC.

JUN 29 1998

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

Supplement Requiring Prior-Approval

NDA NO _____ REF NO. 5C015

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

NDA SUPPL NO. Package Insert

Dear Sir/Madame:

Background

- Reference is made to our 3 for GRIFULVIN V (griseofulvin oral suspension) microsize.
- Reference is made to our approved Abbreviated Antibiotic Drug Application 62-483 for GRIFULVIN V (griseofulvin oral suspension) microsize.
- our supplier of child resistant closures for GRIFULVIN V Oral Suspension that they have undergone a catalyst conversion for their resins.
- also changed their additive package. This antioxidant package change will provide a resin with improved organoleptics and will be a substantial improvement in resin stability technology. They will be using commercially available antioxidants at levels consistent with those used throughout the industry and well below maximum usage allowable in 21 CFR 178.2010.

Resin Change

- currently uses the resin, to mold their Clic-Loc Child Resistant Closures which is used for GRIFULVIN V Oral Suspension.
- The resin currently uses for the cap will be replaced by a High Activity Catalyst version H1200NS.

Antioxidant Change

- The current resin, contains as primary antioxidants and a as a secondary antioxidant. resin, removes the and adds as a secondary antioxidant.

Purpose of the submission

- We are filing this prior approval supplement under 21 CFR 314.70(b)(2)(vii) to gain approval for the Clic-Loc Child Resistant Closure manufactured with resin

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Continued on next page

RECEIVED

JUN 30 1998

GENERIC DRUGS

199 Grandview Road, Skillman, NJ 08558-9418 (908) 874-1000

DMF Cross reference

- Appended is a copy of a letter from , who have updated their DMF to include the version of authorizing the FDA to refer to their Drug Master File for the Clic-Loc Child Resistant Closure on behalf of Johnson & Johnson Consumer Companies, Inc.
- Appended is a copy of a letter from authorizing the FDA to refer to their Drug Master File for the Clic-Loc Child Resistant Closure on behalf of Johnson & Johnson Consumer Companies, Inc.
- has consolidated their products into a single Drug Master File . Appended is a copy of a letter from authorizing FDA to refer to DMF on behalf of Johnson & Johnson Consumer Companies, Inc.

Qualification of the new Cap

- Appended are supporting data confirming the equivalency of the cap with the resin changes.
- Three months of stability data are provided on GRIFULVIN V Suspension packaged with the new cap, upright and inverted, at 5°C, 25°C/60%RH and 40°C.
- Data is also provided on the same lot of product packaged using our current, approved cap.
- The stability of the product with the new cap is equivalent to the stability in the current package.
- We will continue to monitor this batch on stability until its expiration date and report the data in the annual report.

District Copy

- In accordance with 21 CFR 314.71(b) a copy of this supplement is being sent to the New Jersey District Office.

Timing

- will no longer manufacture the currently approved cap for us.
- We have enough caps to last until the end of the year, at which time we need to introduce the new cap.
- We respectfully request that FDA review and approve this supplement before year-end 1998.

Continued on next page

Questions

In the interim, should you have any questions, please contact me:

▪ Directly	(908) 874-1296
▪ Our phone number dedicated for FDA use	(908) 874-1700
▪ Fax	(908) 874-1118
▪ E-mail	lgryzie@cpcus.jnj.com

Sincerely,

Lewis Gryziewicz
Manager
Regulatory Affairs