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OK to file
JMS 2/7/84

ORTHO

ORTHO PHARMACEUTICAL CORPORATION
Raritan, New Jersey 08869

FEB 1 1984

Antibiotic Drug Review Branch (HFN-535)
Attention: Marvin Seife, M.D.
Division of Generic Drugs
National Center for Drugs & Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Subject: Form 6 #62-483

Gentlemen:

Reference is made to the subject Antibiotic Form 6 application for GRIFULVIN V* (griseofulvin microsize) Suspension and, specifically, to your approval letter of January 26, 1984.

In the sixth paragraph of that letter under the heading "For Initial Campaigns", you requested us to submit, in draft form, any proposed advertising or promotional copy which we intend to use in our immediate advertising or promotional campaigns.

Actually, we are already considerably beyond the initial campaign stage, having been approved on February 15, 1980, as a distributor of GRIFULVIN V Suspension under McNeil's Form 5 #50-448. During the last four years, our advertising and promotional labeling have been submitted at the time of initial use, in duplicate and with a completed Form FD 2253 as required by 21 CFR 431.60(b)(3), to Form 5 #50-448 (to which reference is made for examples of our previously submitted advertising and promotional labeling).

Incidentally, Ortho is now also the sponsor of that Form 5, having assumed all responsibility for it from McNeil through submitted correspondence dated July 1, 1980.

Henceforth, we plan to use the subject Form 6 as the repository for the kinds of information required by 21 CFR 431.60 and to merely update Form 5 #50-448 by reference. We trust that this will be satisfactory.

Very truly yours,

ORTHO PHARMACEUTICAL CORPORATION

A. J. Vazakas

by: A. J. Vazakas, Ph.D.
Manager of Regulatory Affairs

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*Trademark

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