CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

62483

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Our reference: 62-483

Ortho Pharmaceutical Corporation
Attention: A. J. Vazakas, Ph.D.
Raritan, New Jersey 08869

JAN 26 1984

Gentlemen:

Please refer to your Antibiotic Form 6 application dated September 28, 1983, for Grifulvin V (griseofulvin microsize) Suspension.

Please also refer to your submission dated January 12, 1984, which satisfactorily responds to our letter dated January 4, 1984.

We have completed our review of this application and it is approved.

An expiration date of twenty-four (24) months should be used on each batch of the drug to be marketed and packaged as described in the application.

Place drug samples from the first three production batches into your stability program and test each batch at three (3) month intervals during the first year of aging, at six (6) month intervals during the second year, annually thereafter. As the data become available they should be furnished to this office at six (6) month intervals throughout the authorized shelf life of the subject drug.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form not final printed. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Advertising and Labeling (HFN-240). Also, please do not use Form FD-2253 for this submission.

For Subsequent Campaigns: We call your attention to regulation 21 CFR 431.60(b)(3) which requires that all material for any subsequent advertising or promotional campaigns at the time of their initial use be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed Form FD-2253. A copy of Form FD-2253 is enclosed for your convenience.

Please be reminded that since you are manufacturing the subject drug for the first time, that 21 CFR 431.60 requires that certain records and reports be submitted following the date of marketing of a batch at three (3) month intervals during the first year, at six (6) month intervals during the second year, and annually thereafter.

The Form 6 should be kept up to date by submitting amendments whenever changes are contemplated in the manufacturing and/or laboratory procedures, controls, equipment and instrumentation, key scientific and production personnel, packaging, labeling, source of antibiotics, etc.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
National Center for Drugs and Biologics

1/26/84

Enclosure

HFK-DO (HFR-2300)