CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 86-766

APPROVAL LETTER

NOV 11 1981

NDA 86-766

Wanot Laboratories, Inc.
Attention: Mr. Gregory P. Bergt
100 Nancy Drive
Belle Plaine, MN 56011

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrofurazone 0.2% Ointment.

Reference is also made to your communication dated March 23, 1981.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

However, at time of the next printing or 180 days, whichever occurs first, revise the package inserts as per our letter of September 18, 1980 and add dispensing information as per Federal Register Notice of August 10, 1979.

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

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 both copies and a completed form FD-2253, together with a copy of the Final Printed Labeling, to the Division of Drug Advertising (HFD-170). A copy of form FD-2253 is enclosed for your convenience.

We call your attention to regulation 21 CFR 310.300 (b)(3) [or 431.60(b)(3) if Form 6] which requires that material for any subsequent advertising or promotional campaigns, at the time of their initial use, be submitted to our Division of Drug Advertising (HFD-170) with a completed form FD-2253.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

Marvin Seife 5/11/81

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements
Form FD2253

cc:
MINN-DO
HFD-313
HFD-530
AStandard/JLMeyer/CChang e.c. 5-7-81
R/D init JLMeyer/MSeife/5/6/81
pb/5/7/81
approval
2396E

JLMeyer 5/8/81