CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-045

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

241

DIV

MAY 13 1988

NDA 8-693/S-025
NDA 9-175/S-019
NDA [redacted]

Mr. A.C. Ilse
Norwich Eaton Pharmaceuticals, Inc.
P.O. Box 191
Norwich, NY 13815

Dear Mr. Ilse:

Reference is made to your supplemental New Drug Applications (NDAs) dated January 14, 1988, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Furadantin Tablets (NDA 8-693), Furadantin Oral Suspension (NDA 9-175), and Macrodantin (NDA 16-620).

These supplements provided revised package inserts with modifications to the information dealing with pulmonary reactions associated with nitrofurantoin.

We have completed our review of these supplemental applications and they are approved with the following labeling revision:

> In the "ADVERSE REACTIONS" section, the word "Respiratory" should be placed on a separate line so that it is more prominent. It should be kept in boldface type.

This revision should be incorporated in the next printing.

[ ]

This revision should be implemented and the "Dear Doctor" letter mailed within 10 days.

Our comments are limited to the proposed changes requested in this supplement. Subsequent labeling revisions which have been approved or are pending approval are not affected and are not addressed here.

Sincerely yours,

Edward Tabor, M.D.
Director
Division of Anti-Infective
Drug Products
Office of Biologics Research and Review
Center for Drugs and Biologics

cc:
ORIG. NDA 8-693/S-025
ORIG. NDA 9-175/S-019
ORIG. NDA 16-628/S-045
HFN-80
HFN-800/RNelson, Ph.D.
HFN-815 ET 5/6/88
HFN-815/CSO/PDesantis/JMazario/3/3/88/adj/3/3/88
HFN-815/MO/MSAlbourne/3/11/88 MSA 4/22/88
HFN-815/PHARM
HFN-815/SRT/JEckert
HFN-366/Walter Brown/Regulatory Affairs
HFN-366/Dave Reed/Regulatory Affairs
F/D: 3/11/88/4/20/88
F/T: 3/11/88/4/20/88
1303m