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APPLICATION NUMBER:

16-620 / S-047

APPROVAL LETTER

16620

JAN 3 1989

NDA 16-620/S-047

Mr. Arthur C. Ilse
Regulatory Affairs
Norwich Eaton Pharmaceuticals, Inc.
P. O. Box 191
Norwich, NY 13815

Dear Mr. Ilse:

Please refer to your supplemental New Drug Application dated December 5, 1988, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macrodantin (nitrofurantoin macrocrystals), 25, 50, and 100 mg.

The supplemental application provides for [redacted] to be alternate contract packagers for the drug product in the 25, 50 and 100 mg strengths in blister packs.

We have completed our review of this supplemental application and it is approved. Our previous letters have detailed the conditions relating to the approval of this application.

Sincerely yours,

ARC

Armand R. Casola, Ph.D.
Supervisory Chemist
Division of Anti-Infective
Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Orig NDA 16-620/S-047
HFD-520
HFD-520/CSO/Fabritzky
HFD-520/MO/Alpert
HFD-520/De Camp/gm 11-23/88 WB 12/28/88
HFD-82
HFD-520/Buko
HFD-520/Gavrilovich
R/D init. by ARCasola 12-23-88 ARC 12/29/88
1251c
APPROVED