CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 7337/S24

APPROVAL LETTER

NDA 7-337/S024

Medical Products Department
E.I. DuPont de Nemours & Company
Barley Mill Plaza, P27-2260
Wilmington, Delaware 19880-0027

JUN 14

Attention: Edward B. Adams
Senior Regulatory Affairs Consultant

Dear Mr. Adams:

Please refer to your May 11, 1989 supplemental new drug application received May 17, 1989 under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Percodan (oxycodone HCl, aspirin).

The supplemental application provides for an additional warning regarding the drug abuse and dependence potentials of Percodan. This strengthens current labeling.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact:

Mrs. Mary L. Owens
Project Manager
Pilot Drug Evaluation Staff, HFD-007
Telephone (301) 443-3741

Sincerely yours,

Carl C. Peck, M.D.
Director
Center for Drug Evaluation and Reserch

cc:
Orig.NDA 7-337/S024
HFD-7/Division File
HFD-80
HFD-7mlowens, CSO, 6-12-89
R/D Init. by:DWPease SCSO/DWPease 6/12/89
F/T by: KAH 6/12/89 (Wang # 4186P)

APPROVAL

6-13-89

HFD1 / cc Peck