CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 7337/S24

CORRESPONDENCE

ME-7

Orig

REGISTERED MAIL
RETURN RECEIPT REQUESTED

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

MEDICAL PRODUCTS DEPARTMENT

May 11, 1989

NDA NO. 7-337 REF. NO. SLF-024

NDA SUPPL FOR FPL

Strengthens current labeling. Acceptable.
FV.
5/26/89

Division of Neuropharmacological Drug Products
Center for Drugs and Biologics
Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

007

RE: NDA No. 7-337; Percodan®/Percodan®-Demi Tablets
SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

Gentlemen:

In accordance with Section 314.70 (3)(c)(2)(ii) of the Code of Federal Regulations, Title 21, we are providing for a change in the package insert for the addition of the following section and statement:

Drug Abuse and Dependence

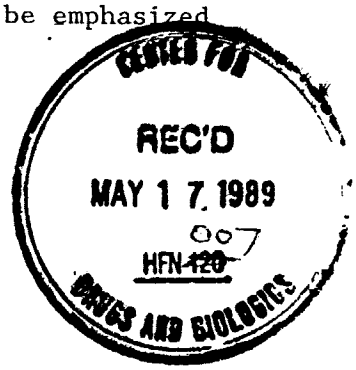
> Percodan® Tablets are a Schedule II controlled substance. Oxycodone can produce drug dependence and has the potential for being abused (see Warnings).

We realize that the Agency has stayed the effective date for the analgesic labeling for "Content and Format for Labeling of Human Prescription Drugs" which was published in the FEDERAL REGISTER on June 26, 1979 (44FR 37443-37467) which included this section.

As you know oxycodone is a Schedule II narcotic drug which has a potential for abuse in addition to psychic and physical dependence. The information included in this revised package insert which appears in the "Warnings" section is perhaps redundant, however, we believe the information should be emphasized and reinforced to the practitioner.

The insert will be effected July 1, 1989.

Enclosed are twelve copies of the revised insert.



Sincerely,

Edward B. Adams
Senior Regulatory Affairs Consultant
(302) 992-5094

EBA:prc
Enclosure
Submitted in Duplicate