

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 7337/S24

ADMINISTRATIVE DOCUMENTS

CSO Review of Final Printed Labeling

NDA 7-337/S024

Package insert and patient information revised January 1989.

I have reviewed the latest revisions requested for Percodan; all changes are made as requested.

S024 is an additional warning about the potential for drug abuse and dependence. This addition strengthens current labeling.

Approval letter has been drafted. CSO will sign off on labeling when it is processed.

/S/

Mary L. Owens, CSO

/S/

4/13/89

Dottie W. Pease, Acting SCSO

cc: NDA 7-337/S024
Div File/ HFD 7
mLowens, CSO/HFD 7
DWPease, SCSO/HFD7

WANG 4185P

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE <i>(Title 21, Code of Federal Regulations, 314)</i>		Form Approved: OMB No. 0910-0001 Expiration Date: May 31, 1986.	
		FOR FDA USE ONLY	
		DATE RECEIVED	DATE FILED
		DIVISION ASSIGNED	NDA/ANDA NO. ASS.
NOTE: No application may be filed unless a completed application form has been received (21 C.F.R. Part 314).			
NAME OF APPLICANT Du Pont Pharmaceuticals		DATE OF SUBMISSION May 11, 1989	
ADDRESS (Number, Street, City, State and Zip Code) Barley Mill Plaza, P27-2260 Wilmington, Delaware - 19880-0027		TELEPHONE NO. (Include Area Code) (302) 992-5094	
NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued) NDA No. 7-337			
DRUG PRODUCT			
ESTABLISHED NAME (e.g., USP/USAN) Oxycodone HCl, Aspirin		PROPRIETARY NAME (If any) Percodan®/Percodan®-Demi Tablets	
CODE NAME (If any)	CHEMICAL NAME 14-hydroxydihydrocodeinone		
DOSAGE FORM Tablets	ROUTE OF ADMINISTRATION Oral	STRENGTH(S) oxycodone 5mg Aspirin 325 mg	
PROPOSED INDICATIONS FOR USE Percodan® is indicated for the relief of moderate to moderately severe pain.			
LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:			
INFORMATION ON APPLICATION			
TYPE OF APPLICATION (Check one)			
<input type="checkbox"/> THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50)		<input type="checkbox"/> THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)	
IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION			
NAME OF DRUG		HOLDER OF APPROVED APPLICATION	
STATUS OF APPLICATION (Check one)			
<input type="checkbox"/> ORIGINAL APPLICATION <input type="checkbox"/> AN AMENDMENT TO A PENDING APPLICATION		<input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SUPPLEMENTAL APPLICATION	
PROPOSED MARKETING STATUS (Check one)			
<input type="checkbox"/> APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)		<input type="checkbox"/> APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)	