CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40199

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 40-199 Date of Submission: July 9, 1996

Applicant's Name: Amide Pharmaceutical, Inc.

Established Name: Oxycodone and Acetaminophen Capsules USP, 5 mg/500 mg.

Labeling Deficiencies:

1. CONTAINER (100's and 1000's)

   a. Please note that the controlled substance symbol must be at least twice as large as the largest type otherwise printed on the label. Alternatively, the symbol may be overprinted on the label, in which case the symbol must be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label. Please revise to be in accord with 21 CFR 1302.04.

   b. Position the strengths of the active ingredients to appear in conjunction with the established name of your product on the main display panel.

   c. ...as defined in the USP.

2. INSERT

   a. GENERAL COMMENT

      Revise, to read, "oxycodone and acetaminophen capsules" throughout the package insert labeling. Also, "oxycodone and acetaminophen capsules" may be revised to appear in lower case letters where it appears.

   b. DESCRIPTION

      i. Each capsule for oral administration contains:

      ii. ...pregelatinized starch...

      iii. Please include a listing of dye(s), if any, present in the imprinting ink.

iv. Include the chemical name of acetaminophen as it appears in the monograph for acetaminophen in USP 23, 4'-hydroxyacetanilide.

c. PRECAUTIONS

i. General (Penultimate line)

"hypothyroidism", (spelling)

ii. **Pregnancy**

Teratogenic Effects: Pregnancy Category C:

a) Revise this subsection heading as above.

b) Make the following revision in the last sentence, "...may produce physical dependence...".

iii. Labor and Delivery

This subsection heading should appear with the same format as other subsection headings, e.g., on a line by itself and without the colon.

iv. Nursing Mothers

a) Delete colon following subsection heading.

b) ...whether the components of oxycodone and acetaminophen capsules are...

v. Pediatric Use

a) Delete colon following subsection heading.

b) ...in pediatric patients have...

d. OVERDOSAGE

i. Acetaminophen

a) Signs and Symptoms

Combine the second and third paragraphs.

b) Treatment

Make the following revision in the second sentence, "Patients'

estimates...".

ii. Oxycodone (Treatment)

Make the following revision in the second sentence of the first paragraph, "...antagonist naloxone...".

e. HOW SUPPLIED

i. Include the strength of your product in this section.

ii. We encourage the inclusion of NDC numbers in this section.

iii. We encourage the inclusion of the, "Caution: Federal law..." statement in this section.

iv. Include the revision date for the package insert in this section.

v. See comment "c." for CONTAINER.

vi. Revise storage temperature to read, "...15°-30°C (59°-86°F)".

Please prepare and submit final printed container labels and package insert labeling.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon further changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

/S/

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research