CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40191

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 40-191 Date of Submission: June 4, 1996; July 8, 1996; and August 22, 1996

Applicant's Name: Vintage Pharmaceuticals, Inc.

Established Name: Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg

Labeling Deficiencies:

1. CONTAINER (100s)

   Satisfactory

2. INSERT

   a. Include the controlled substance symbol with prominence in the upper right hand corner of the package insert. We refer you to 21 CFR 1302.05 for guidance.

   b. DESCRIPTION

      i. Please include the structural formula, chemical formula, and molecular weight for meperidine hydrochloride in this section.

      ii. Combine the second and third paragraphs and revise as follows:

      Each tablet, for oral administration, contains 50 mg or 100 mg meperidine hydrochloride. In addition, each tablet contains the following inactive ingredients...

   c. CLINICAL PHARMACOLOGY

      Add the following text as the last two sentences of this section:

      Meperidine, in 60 mg to 80 mg parenteral doses, is approximately equivalent in analgesic effect to 10 mg of morphine. The onset of action is slightly more rapid than with morphine, and the duration of action is slightly shorter.

Meperidine is significantly less effective by the oral than by the parenteral route, but the exact ratio of oral to parenteral effectiveness is unknown.

d. INDICATIONS AND USAGE

Meperidine hydrochloride tablets USP are indicated for...

e. WARNINGS

Delete the penultimate paragraph, as the tablets do not have this indication.

f. ADVERSE REACTIONS

i. Nervous System

Delete the adverse reaction, as it does not appear in the approved labeling of the listed drug.

ii. Cardiovascular

...(see WARNINGS)...

iii. Add the following as the last subsection:

Other. Antidiuretic effect.

g. DOSAGE AND ADMINISTRATION

i. Relocate this section so that it follows the OVERDOSAGE section and precedes the HOW SUPPLIED section.

ii. Regarding the first line, this subsection heading may be deleted since oral meperidine is only indicated for pain.

h. OVERDOSAGE (Symptoms)

Make the following revision in the last sentence, "...overdosage, particularly by the intravenous route, apnea, circulatory...".

i. HOW SUPPLIED

i. We encourage the inclusion of the established name of your product in this section.

ii. Please include appropriate information in this section to facilitate identification of your tablets such as shape, color, scoring, and the National Drug Code. We refer you to 21 CFR 201.57(k)(3) for guidance.

In addition, please include information regarding the tablet imprints for your product which in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. We refer you to 21 CFR 206.10(a) for guidance.

iii. We encourage the inclusion of storage and dispensing recommendations in this section which are consistent with those found on your container labels.

iv. Please also include the "CAUTION: Federal law..." statement in this section as it appears on your container labels.

Please prepare and submit final printed labels and labeling.

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.

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.

/S/

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

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

ANDA Number: **40-191** Date of Submission: **March 20, 1997**

Applicant's Name: **Vintage Pharmaceuticals, Inc.**

Established Name: **Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg**

Labeling Deficiencies:

1. CONTAINER (100s)

   Relocate the statement "WARNING: May be habit forming.", to immediately follow the established name on the principal display panel. We refer you to 21 CFR 329.10(c) for further guidance.

2. INSERT

   a. ADVERSE REACTIONS, Nervous System - ... uncoordinated muscle movements, severe convulsions, transient hallucinations ...

   b. DOSAGE AND ADMINISTRATION

      Delete the second sentence of the first paragraph.

   c. HOW SUPPLIED

      Please describe your 100 mg tablet as unscored.

Please revise your container labels and insert labeling, as instructed above, and submit final print.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon 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