CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40251

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 40-251 Date of Submission: March 10, 1997

Applicant's Name: Mikart Inc.

Established Name: Trihexyphenidyl Hydrochloride Elixir USP, 2 mg/5 mL

Labeling Deficiencies:

1. CONTAINER 473 mL (16 fl oz)

   a. The expression of strength should follow the established name. In addition, we encourage the inclusion of "USP" in the established name:

      Trihexyphenidyl Hydrochloride Elixir USP, 2 mg/5 mL

   b. ... (15 to 25 mL) ... [replace hyphen with "to"].

   c. Include "This package not for household dispensing."

   d. We encourage you to reverse the order of the declaration of net quantity so that the "16 fl oz" appears in the parentheses. (Please note - insert "fl" as part of the declaration of net quantity.

2. INSERT

   a. GENERAL COMMENT

      Replace and " with "trihexyphenidyl" throughout the insert except in the TITLE, DESCRIPTION, INDICATIONS AND USAGE and HOW SUPPLIED sections and elsewhere as indicated below.

   b. TITLE

      We encourage the inclusion of "USP" in the established name.

c. DESCRIPTION

i. Revise this section to read:

Trihexyphenidyl Hydrochloride Elixir, for oral administration, is a synthetic antispasmodic drug.

Each 5 mL contains 2 mg trihexyphenidyl hydrochloride and alcohol 5% in a clear, colorless, lime-mint flavored preparation. In addition, it contains the following inactive ingredients: Citric Acid, Flavoring, Methylparaben, Propylparaben and Sorbitol Solution.

Trihexyphenidyl Hydrochloride is a white or slightly off white, crystalline powder, having not more than a very faint odor.

Trihexyphenidyl Hydrochloride is the substituted piperidine salt, [insert the second chemical name found in the USP monograph]. It has the following structural formula:

ii. We encourage inclusion of the pH range.

d. CLINICAL PHARMACOLOGY

Revise the first sentence to read as follows:

Tihexyphenidyl exerts a direct...

e. INDICATIONS

i. Revise this section heading to read "INDICATIONS AND USAGE".

ii. Trihexyphenidyl Hydrochloride Elixir is indicated...

f. WARNING

Revise this section heading to read "WARNINGS" [plural].

g. PRECAUTIONS

Paragraph one - Begin a new paragraph with the second sentence "Since the use of ...".

h. DOSAGE AND ADMINISTRATION

i. Trihexyphenidyl in Idiopathic Parkinsonism

A) Please note subsection heading revision.

B) First sentence - ... 1 mg of trihexyphenidyl hydrochloride may be ... (Delete ').

ii. Trihexyphenidyl in Drug-Induced Parkinsonism

A) Please note subsection heading revision

B) First sentence - ...dose of trihexyphenidyl hydrochloride needed (Delete

iii. Concomitant Use of Trihexyphenidyl with Levodopa.

A) Please note subsection heading revision.

B) Last sentence - Trihexyphenidyl hydrochloride dosage...(Delete

i. HOW SUPPLIED

i. Add "DO NOT FREEZE" to the storage recommendation statement.

ii. We encourage you to either use the term "Manufactured for" or "Distributed by" on both the insert and the container labels for consistency.

iii. Revise the declaration of net quantity for the package size to read "... in 473 mL (16 fl oz) bottles, ..."

iv. Please revise "lime-mint" to read "lime-peppermint".

Please revise your labels and labeling, as instructed above, and submit final printed container labels and draft insert labeling (or final print, if you prefer).

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.

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