

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40230

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 40-230 Date of Submission: December 19, 1996

Applicant's Name: Lannett Company Inc.

Established Name: Dicyclomine Hydrochloride Tablets
USP, 20 mg

Labeling Deficiencies:

1. CONTAINER - 30s, 100s and 1000s

Satisfactory in final print.

2. INSERT

Minor revisions are indicated in the enclosed "mock-up" of your proposed draft labeling. Additional comments follow.

a. DESCRIPTION

- i. First paragraph, third sentence - Revise to read:

In addition, each tablet contains the following inactive ingredients:

- ii. Revise the chemical name to read the same as the second name listed in USP 23.
- iii. Inactive Ingredients
 - A) Revise to read "Pregelatinized Starch" rather than "Starch".
 - B) Revise to read "Anhydrous Lactose" rather than "Lactose".
 - C) Revise to read "Compressible Sugar (sucrose and maltodextrin)" rather than "Compressible Sugar and Malto-Dextrin".

b. DRUG ABUSE AND DEPENDENCE

Revise this section to read:

Abuse of and/or dependence on dicyclomine for anticholinergic effects have been rarely reported.

c. HOW SUPPLIED

i. Revise the first paragraph to read:

Dicyclomine hydrochloride tablets, 20 mg are round,...

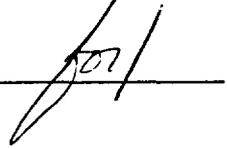
ii. Indicate your tablets are unscored.

iii. Include the "CAUTION: Federal Law prohibits..." statement.

Please revise your insert labeling, as instructed above, and submit final printed labeling.

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.

JSI


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

Enclosure: Mock-Up Labeling

RECORD OF TELEPHONE CONVERSATION

<p>I phoned the firm at the request of the team leader to request that they commit to narrow their in-process blend homogeneity specification to $\frac{1}{2}$ RSD NMT $\frac{1}{2}$, in accordance with recent OGD internal recommendations. Mr. Milkijanic agreed to submit a commitment to revise this specification prior to approval.</p>	<p>DATE 1/13/99</p>
	<p>ANDA NUMBER ANDA 40-230</p>
	<p>IND NUMBER</p>
	<p align="center">TELECON</p>
	<p>INITIATED BY X MADE APPLICANT/ BY SPONSOR TELE.</p>
	<p>X FDA _ IN PERSON</p>
	<p>PRODUCT NAME Dicyclomine Hydrochloride Tabs</p>
	<p>FIRM NAME Lannett Company</p>
	<p>NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Vlad Milkijanic</p>
	<p>TELEPHONE NUMBER (215) 333-9000</p>
<p>SIGNATURE Karen Bernard</p> <p align="right">/s/ 1/13/99</p>	