CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40032

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: **40-032** Date of Submission: **April 3, 1998**

Applicant's Name: **Roxane Laboratories, Inc.**

Established Name: **Cyclophosphamide Tablets USP, 25 mg and 50 mg**

Labeling Deficiencies:

1. UNIT DOSE BLISTER (25 mg and 50 mg)

   Satisfactory in draft.

2. UNIT DOSE CARTON (20s)

   a. Revise to read "Usual Dosage: See package insert...".

   b. Include a statement as to whether or not the unit-dose package is child-resistant. If it is not child-resistant, we encourage the inclusion of a statement that if dispensed to outpatients, it should be with a child resistant container, e.g.,:

      The unit-dose package is not child-resistant. If dispensed for outpatient use, a child-resistant container should be utilized.

      [Note: The second sentence is optional.]

3. CONTAINER (100s)

   See comment (a) under UNIT DOSE CARTON.

4. INSERT

   a. DESCRIPTION

      i. To be in accord with USP 23 revise the molecular weight to read "279.10" rather than

ii. Relocate the first paragraph to appear as the first 2 sentences of the last paragraph and revise to read as follows:

Each tablet for oral administration contains cyclophosphamide...In addition each tablet contains the following inactive ingredients...

iii. Chemical name - Capitalize the "B" in "Bis" and italicize the "*H*" in "2*H*".

iv. Inactive ingredients - Lactose is the subject of two USP monographs. Please revise accordingly.

b. INDICATION AND USAGE

i. Revise this section heading to read:

INDICATIONS AND USAGE

ii. Malignant Diseases - Revise to read "Cyclophosphamide tablets, although" in the first paragraph.

iii. Nonmalignant Disease - Revise to read "Cyclophosphamide tablets are useful...".

c. HOW SUPPLIED

Revise to read...round, unscored tablets...

Please revise your container labels, unit dose carton and labeling, as instructed above, 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 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.

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Jerry Phillips
Director
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Office of Generic Drugs
Center for Drug Evaluation and Research