CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40279

ADMINISTRATIVE DOCUMENTS

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

AND Number: **40-279** Date of Submission: **October 3, 1997**

Applicant's Name: **Fujisawa USA, Inc.**

Established Name: **Fluorouracil Injection USP, 50 mg/mL, 500 mg and 1 g single dose vials**

Labeling Deficiencies:

1. CONTAINER 500 mg and 1 g

   a. We encourage you to differentiate your product strengths with the use of boxing, contrasting colors or some other means.

   b. Revise to read "Store at controlled room...".

   c. Include the statement "Discard Unused Portion".

2. CARTON (1 x 500 mg and 1 x 1 g)

   See comments under container.

3. INSERT

   a. DESCRIPTION

      Include the molecular formula.

   b. CLINICAL PHARMACOLOGY

      Revise the first sentence of paragraph three to read as follows:

      Seven to 20 percent of...

   c. WARNINGS

      Revise to read "5-fluorouracil" rather than "5-FU" in the third paragraph. [3 places]

   d. PRECAUTIONS

i. Drug Interactions, second paragraph - ...WARNINGS section.

ii. Pregnancy - ...WARNINGS section.

iii. Pediatric Use - ...in pediatric patients have...

e. DOSAGE AND ADMINISTRATION

i. Revise the first sentence of paragraph one to read as follows:

12 mg/kg...

ii. Paragraph two - ...WARNINGS sections) should...

iii. Maintenance Therapy, number 2 - Revise to read "g" rather than "gm".

f. HOW SUPPLIED

Store at controlled room...

Please revise your container labels, carton and insert 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.

/S/

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