CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75211

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: **75-211** Date of Submission: **September 29, 1997**

Applicant's Name: **Mylan Pharmaceuticals Inc.**

Established Name: **Acyclovir Tablets, 400 mg and 800 mg**

Labeling Deficiencies:

1. GENERAL COMMENT:

   As a result of the FDA Modernization Act of 1997, the statement "CAUTION: Federal law..." must be replaced with the symbol "Rx only" or "℞ only" throughout your labels and labeling. We refer you to the Guidance For Industry, "Implementation of Section 126, Elimination of Certain Labeling Requirements...", at the internet site: **http://www.fda.gov/cder/guidance/index.htm** for guidance.

2. CONTAINER 100s and 500s (400 mg and 800 mg)

   a. See GENERAL COMMENT above.

   b. Revise the dispensing statement to read:

      "Dispense in a tight container as defined in ..."

   c. Revise the storage temperature statement to read:

      "STORE BETWEEN 15° and 30°C (59° and 77°F)."

   d. Revise to read: **"PROTECT FROM MOISTURE."**

3. INSERT

   a. GENERAL COMMENT

      The words "*in vitro*" and "*in vivo*" must be in italic print wherever they occur in the text of the insert.

b. DESCRIPTION

i. The sentence "Each capsule contains ..." begins a new paragraph.

ii. We encourage you to revise the sentence referred to above to be the same format as that which is used for the tablet descriptor paragraphs, i.e., "Each 200 mg capsule contains 200 mg of acyclovir and ...".

c. INDICATIONS AND USAGE

Herpes Zoster Infections - Acyclovir is indicated for the acute treatment of ... (delete "for the treatment").

d. PRECAUTIONS

Carcinogenesis, Mutagenesis, Impairment of Fertility, Sixth paragraph - "...corpora..." rather than "corpea".

e, DOSAGE AND ADMINISTRATION

Last sentence - ... to four 200 mg capsules ...

f. HOW SUPPLIED

i. See GENERAL COMMENT (1) above.

ii. Please indicate that your tablets are unscored (... biconvex, unscored tablet ...)

iii. Delete the word from the description of the 800 mg tablet.

iv. See comments under CONTAINER above.

Please revise your container labels and insert labeling, as instructed above, and submit 12 copies of each in 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.

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/ for

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