DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-059/S-007

31 AUG 2001

Fujisawa Healthcare, Inc.
Attention: Mr. Donald R. Peckels
Parkway North Center
3 Parkway North
Deerfield, IL 60015-2548

Dear Mr. Peckels:

Please refer to your supplemental new drug application dated July 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adenoscan (adenosine) 3 mg/ml Injection.

We acknowledge receipt of your submission dated January 16, 2001. Your submission of January 16, 2001 constituted a complete response to our July 31, 2000 approvable letter.

This supplemental new drug application provides for final printed labeling revised as follows:

1. Under **PRECAUTIONS/Drug Interactions**, the word "alkylxanthines" has been changed to "methylxanthines" in the first sentence of the second paragraph.

2. Under **PRECAUTIONS/Carcinogenesis, Mutagenesis, Impairment of Fertility**, the second paragraph has been changed to:

   > Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. Fertility studies in animals have not been conducted with adenosine.

3. Under **PRECAUTIONS**, the proposed **Geriatric Use** subsection has been changed to read as follows:

   > Clinical studies of Adenoscan did not include sufficient numbers of subjects aged younger than 65 years to determine whether they respond differently. Other reported experience has not revealed clinically relevant differences of the response of elderly in comparison to younger patients. Greater sensitivity of some older individuals, however, cannot be ruled out.

4. The word "injection" has been added after the word "adenosine" throughout the package insert. Please make this corresponding change in the carton/container labeling at the time of your next printing. This change should reported in your annual report.

5. Under **HOW SUPPLIED**, the statement: "**CAUTION**: Federal law prohibits dispensing without prescription." has been replaced with "**Rx only**."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed package insert included in your January 16, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 594-5311

6Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research