DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020059/S-014 **SUPPLEMENT APPROVAL**

Astellas Pharma US, Inc.
Attention: Donald L. Raineri, Pharm.D.
Three Parkway North
Deerfield, IL 60015-2548

Dear Dr. Raineri:

Please refer to your supplemental new drug applications dated May 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adenoscan (adenosine) 3 mg/mL Injection.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. Under WARNINGS/Sinoatrial and Atrioventricular Nodal Block, the following sentence has been deleted:

   All episodes of AV block have been asymptomatic, transient, and did not require intervention.

2. Under WARNINGS, the following subsection has been added:

   Atrial Fibrillation
   Atrial fibrillation has been reported in patients (with and without a history of atrial fibrillation) undergoing myocardial perfusion imaging with adenosine infusion. In these cases, atrial fibrillation began 1.5 to 3 minutes after initiation of adenosine, lasted for 15 seconds to 6 hours, and spontaneously converted to normal sinus rhythm.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on May 13, 2009.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Russell Fortney, Regulatory Project Manager, at (301) 796-1068.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20059	SUPPL-14	ASTELLAS PHARMA US INC	ADENOSCAN

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
11/06/2009