DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-937/S-021 and 20-059/S-011

Astellas Pharma US, Inc.
Attention: Manfred H. Fleschar, Ph.D., RAC
Three Parkway North
Deerfield, IL 60015-2548

Dear Dr. Fleschar:

Please refer to your supplemental new drug applications dated February 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adenocard (adenosine) 3 mg/mL Injection (NDA 19-937) and Adenoscan (adenosine) 3 mg/mL Injection (NDA 20-059).

We acknowledge receipt of your submissions dated July 1, 2005.

These supplemental new drug applications provide for labeling revised as follows:

NDA 19-937 Adenocard

1. The label dates have been updated.

2. The manufacturer's information has been updated as follows:

   Manufactured for:
   Fujisawa Healthcare, Inc.
   Deerfield, IL 60015

   Has been replaced with:

   Marketed by:

   Astellas Pharma US, Inc.
   Deerfield, IL 60015 240

   Manufactured by:

   Hospira, Inc.
   Lake Forest, IL 60045 USA

3. Under **ADVERSE REACTIONS**, the following new Post Marketing Experience section has been added:

   Post Marketing Experience (see **WARNINGS**)

   The following adverse events have been reported from marketing experience with Adenoscan. Because these events are reported voluntarily from a population of uncertain size, are associated with concomitant diseases and multiple drug therapies and surgical procedures, it is not always possible to reliably estimate

their frequency or establish a causal relationship to drug exposure. Decisions to include these events in labeling are typically based on one or more of the following factors: (1) seriousness of the event, (2) frequency of the reporting, (3) strength of causal connection to the drug, or a combination of these factors.

Cardiovascular
Prolonged asystole, ventricular tachycardia, ventricular fibrillation, transient increase in blood pressure, bradycardia, atrial fibrillation, and Torsade de Pointes

Respiratory
Bronchospasm

Central Nervous System
Seizure activity, including tonic clonic (grand mal) seizures, and loss of consciousness

NDA 20-059 Adenoscan

1. The label dates have been updated.

2. The manufacturer's information has been updated as follows:

   Manufactured for:
   Fujisawa Healthcare, Inc.
   Deerfield, IL 60015

   Has been replaced with:

   Marketed by:

   Astellas Pharma US, Inc.
   Deerfield, IL 60015 240

   Manufactured by:

   Hospira, Inc.
   Lake Forest, IL 60045 USA

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   Body as a Whole
   Injection site reaction

   Central Nervous System

Seizure activity, including tonic clonic (grand mal) seizures, and loss of consciousness

Digestive
Nausea and vomiting

Respiratory
Respiratory arrest

We have completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the electronic labeling submitted on July 1, 2005.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Norman Stockbridge

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