DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022161/S-006/ S-007/ S-008

SUPPLEMENT APPROVAL

Astellas Pharma US, Inc.
Attention: Michael Silwoski
Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015

Dear Mr. Silwoski:

Please refer to your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lexiscan™(regadenoson) Injection.

- **NDA 22161/S-006** dated June 7, 2011, received: June 8, 2011.

  The June 7, 2011, submission constituted a complete response to our May 24, 2011, action letter. The supplement was submitted November 24, 2010.

  S-006: This "Prior Approval" supplemental new drug application provides for revisions to the **WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, USE in SPECIFIC POPULATIONS AND PHARMACODYNAMICS** sections of the packet insert to include data obtained from the Post-Marketing Requirement safety studies (3606-CL-3001 and 3606-CL-3010).

- **NDA 22161/S-007 and S-008** dated March 31, 2011, received March 31, 2011.

  We acknowledge receipt of your amendment dated April 13, 2011.

  S-007: This "Changes Being Effected" supplemental new drug application provides for revisions to the **ADVERSE REACTIONS** section of the packet insert to include data reported through post-marketing safety surveillance and adverse event reports of hypersensitivity and QTc prolongation.

  S-008: This "Prior Approval" supplemental new drug application provides for revisions to the **PHARMACODYNAMICS** section of the packet insert to include language regarding the ingestion of caffeine prior to subjects undergoing myocardial perfusion imaging (MPI).

We have completed our review of the supplemental applications, as amended. The applications are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (package insert), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-161/ S-006/ S-007/ S-008**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, call Ms. Sharon Thomas, Regulatory Project Manager, at (301) 796-1994.

Sincerely,

{See appended electronic signature page}

Rafel Rieves, M.D.
Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

RAFEL D RIEVES
09/23/2011