DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202611/S-005

SUPPLEMENT APPROVAL

Astellas Pharma Global Development, Inc.
Attention: Judy Kannenberg – Senior Director, Regulatory Affairs
1 Astellas Way
Northbrook, IL 60062

Dear Ms. Kannenberg:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 27, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MYRBETRIQ® (mirabegron) extended release tablets, 25 mg and 50 mg.

We acknowledge receipt of your amendments dated August 24, August 31, and October 9, 2015.

This "Prior Approval" supplemental new drug application proposes to add "nausea" and "pruritus" to the Postmarketing Experience subsection of the ADVERSE REACTIONS section of the Package Insert.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text and with the following minor editorial revisions:

1. In **Section 6.2, Postmarketing Experience**, change the comma that separates the symptoms of angioedema from the word "pruritus" to a semi-colon.

2. In **Subsection 8.1, Pregnancy, Risk Summary**, second sentence, change the word "maximal" in "maximal recommended human dose" to the word "maximum", as in "maximum recommended human dose".

3. In **Subsection 8.1, Pregnancy, Animal Data**, third paragraph, fifth sentence, change "MHRD" to "MRHD" to correctly represent "maximum recommended human dose".

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, please call Nenita Crisostomo, Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
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/

AUDREY L GASSMAN
11/02/2015