

August 15, 2006

**VIA E-MAIL**

Senators Chuck Grassley and Max Baucus  
United States Senate  
Committee On Finance  
219 Dirksen Senate Office Building  
Washington, DC 20510-6200

Re: S. 3155 - Miscellaneous Tariff Bill - Astellas Pharma U.S., Inc. - RSD 1235

Senators Grassley and Baucus:

We are writing in support of S. 3155,<sup>1</sup> a tariff measure currently before your committee for inclusion in the next miscellaneous tariff bill.

As you may know, S. 3155 seeks a duty suspension upon the chemical substance known as RSD 1235. Astellas Pharma U.S., Inc., (“Astellas”), headquartered in Deerfield, Illinois,<sup>2</sup> currently imports this material into the United States from Switzerland. RSD 1235 is an active pharmaceutical ingredient (“API”) used to treat patients experiencing atrial fibrillation. RSD 1235 is currently registered with the U.S. Food and Drug Administration (“FDA”) as the API for a new investigational drug.<sup>3</sup> The material is currently undergoing phase III clinical trials. Astellas anticipates final FDA approval in late 2006.<sup>4</sup>

Although most pharmaceutical substances are eligible for duty-free treatment, RSD 1235 is currently subject to a 6.5% duty rate upon importation into the United States. This material does not qualify for duty-free treatment under the *Harmonized Tariff Schedule of the U.S.* (“HTSUS”) because it is a new product that is in the process of completing its final stages of development, too late for inclusion in the latest pharmaceutical appendix to the HTSUS, which sets forth duty-free treatment for certain named pharmaceutical ingredients.

Based upon the product’s current 6.5% *ad valorem* duty rate, Astellas is at a competitive disadvantage for this pharmaceutical ingredient while its competitors enjoy duty-free treatment, by virtue of the pharmaceutical appendix, for comparable pharmaceutical ingredients. Therefore,

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<sup>1</sup> S. 3155 is attached hereto as **Exhibit A**.

<sup>2</sup> APUS employs approximately 1200 individuals in North America and 350 individuals in Deerfield, Illinois.

<sup>3</sup> IND# 61,848.

<sup>4</sup> New Drug Application (“NDA”) has been filed. See March 31, 2006 press release attached hereto as **Exhibit B**.

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Astellas seeks to suspend duty on RSD 1235 through this proposed tariff legislation until such time as the U.S. Trade Representative adds this item to the pharmaceutical appendix.

In addition to providing uniform duty treatment for this pharmaceutical ingredient, S. 3155 also encourages economic development in certain localities. For instance, we note that after importation, Astellas ships RSD 1235 for further manufacturing to Hospira's drug processing facility in Rocky Mount, North Carolina. As such, S. 3155 not only provides for duty-free status for this material, but also promotes the local economy in North Carolina where Hospira will further manufacture this pharmaceutical substance.

Finally, we note that S. 3155 will result in lower costs to produce this new drug, thereby allowing Astellas to deliver this drug to market in an expeditious and cost effective manner, ultimately benefiting consumers. This is the same objective as the duty-free status which the pharmaceutical appendix is designed to achieve, but for which RSD 1235 has yet to enjoy. We trust S. 3155 will alleviate this concern until such time as RSD 1235 is added to the pharmaceutical appendix.

Based upon the foregoing factors, Astellas encourages quick passage of S. 3155 in the upcoming miscellaneous tariff bill. Should you need any further information concerning RSD 1235, please do not hesitate to contact the undersigned.

Very truly yours,

Astellas Pharma Manufacturing, Inc.

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Encl.