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News Release

August 12, 2009

Update on Astellas' Complaint Challenging the FDA's decision for Citizen Petition in the US

As stated in the press release issued on August 11, 2009, Astellas Pharma US, Inc. ("Astellas Pharma US"; headquarters: Deerfield, IL), North American affiliate of Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori), has received notice that the U.S. Food and Drug Administration (FDA) has substantially denied the company's Citizen Petition*, which had been submitted in September 2007, to ensure the safe and effective use of oral immunosuppressants used in organ transplant patients on August 10, 2009 (local time). In response, Astellas today announced that Astellas Pharma US has filed a complaint in U.S. District Court in Washington, D.C. challenging the FDA's decision and requested the court to issue a Preliminary Injunction and Temporary Restraining Order enjoining the FDA's approval of ANDA(s) for oral immunosuppressant on August 11, 2009 (local time).

*About Citizen Petition
A Citizen Petition is a formal request asking FDA to issue, change or cancel a regulation, or to take other action under the laws administered by the agency. FDA receives about 200 petitions yearly.

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