

August 13, 2009

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

Tokyo, Japan, August 13, 2009- Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that U.S. District Court in Washington, D.C. has denied the Temporary Restraining Order and Preliminary Injunction which have been requested by Astellas' North American affiliate Astellas Pharma US, Inc. ("Astellas Pharma US"; headquarters: Deerfield, IL). The company is disappointed in the court's decision and is currently evaluating its next course of action.

As stated in the press release issued on August 12, 2009, Astellas Pharma US 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 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 an Abbreviated New Drug Application 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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