

November 26, 2009

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

Tokyo, Japan, November 26, 2009 – Astellas Pharma Inc. (headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that its North American affiliate, Astellas Pharma US, Inc. (“Astellas Pharma US”; headquarters: Deerfield, IL) has dismissed its lawsuit against the U.S. Food and Drug Administration (FDA).

As stated in the press release issued on August 13, 2009, Astellas Pharma US filed the lawsuit on August 11, 2009 after FDA substantially denied the company's Citizen Petition regarding the safe and effective use of oral immunosuppressants used in organ transplant patients.

*About Citizen Petition

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

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