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RESEARCH**

*APPLICATION NUMBER:*

**208780Orig1s000**

**STATISTICAL REVIEW(S)**

## STATISTICAL MEMO

<b>NDA #:</b>	208780
<b>Applicant:</b>	Genentech
<b>Name of Drug:</b>	Pirfenidone Film-coated Tablets
<b>Indication:</b>	Idiopathic pulmonary fibrosis (IPF)
<b>Dates:</b>	Submission date: 3/29/16
<b>Statistical Team:</b>	Gregory Levin
<b>Clinical Team:</b>	Courtney McGuire, Anthony Durmowicz
<b>Medical Division:</b>	Division of Pulmonary, Allergy, and Rheumatology Products
<b>Project Manager:</b>	Jessica Lee

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**Summary:** Esbriet (pirfenidone) was approved for the treatment of idiopathic pulmonary fibrosis (IPF) in the United States on October 15, 2014. Pirfenidone is currently marketed as a 267 mg capsule. This is a New Drug Application (NDA) supporting a new film-coated tablet formulation. The application is supported by data from a pharmacokinetic (PK) bioequivalence study (Study GP29830) in healthy volunteers comparing the two formulations. There are no studies evaluating the safety and efficacy of the proposed tablet in IPF patients, so a statistical review of this NDA is not necessary.

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GREGORY P LEVIN  
06/10/2016