



NDA 22535/S-012  
NDA 208780/S-002

## SUPPLEMENT APPROVAL

Genentech, Inc.  
1 DNA Way MS#355F  
South San Francisco, CA 94080-4990

Attention: Chand Sishta, Ph.D.  
Product Development Regulatory Program Management

Dear Dr. Sishta:

Please refer to your supplemental new drug applications (sNDAs) dated July 8, 2019, received, and your amendment(s), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 22535/S-012, Esbriet (pirfenidone) capsules, 267 mg and NDA 208780/S-002, Esbriet (pirfenidone) Film-Coated Tablets, 267 mg, 534 mg and 801 mg.

We also refer to our letter dated June 7, 2018, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Esbriet (pirfenidone). This information pertains to the risk of drug-induced liver injury (DILI) associated with the use of pirfenidone.

This supplemental new drug application provides for revisions to the labeling for Esbriet (pirfenidone), consistent with our June 7, 2019, Safety Labeling Change Notification letter.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling text for the Prescribing Information and Patient Package Insert, with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions, call Carol F. Hill, Senior Regulatory Health Project Manager for Safety, at 301-796-1226.

Sincerely,

*{See appended electronic signature page}*

Sally Seymour, MD  
Director  
Division of Pulmonary, Allergy, and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

- Prescribing Information
- Patient Package Insert

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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SALLY M SEYMOUR  
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