Dear Ms. Nasser:

Please refer to your supplemental new drug applications (sNDAs) dated August 13, 2021, received August 13, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Esbriet (pirfenidone) Capsules and Tablets.

These “Changes Being Effected” sNDAs provide for removing the term ‘anorexia’ and combining the frequency with the preferred term ‘decreased appetite’ under Section 6 Adverse Reactions in the Esbriet USPI.

**APPROVAL & LABELING**

We have completed our review of these applications, 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.\(^1\) 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 Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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\(^1\) [http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm)
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.\(^2\)
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).

**REPORTING REQUIREMENTS**

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

If you have any questions, contact Nina Ton, Senior Regulatory Project Manager, at
(301) 796-1648.

Sincerely,

{See appended electronic signature page}

Robert Lim, MD
Deputy Director for Safety
Division of Pulmonology, Allergy,
and Critical Care
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

**ENCLOSURES:**

- Content of Labeling
  - Prescribing Information
  - Patient Package

\(^2\) We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance
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.

/s/

ROBERT H LIM
02/11/2022 09:48:21 AM