

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208780Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW MEMO

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	September 14, 2016
Application Type and Number:	NDA 208780
Product Name and Strengths:	Esbriet (pirfenidone) film-coated tablets 267 mg and 801 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Genentech
Panorama #:	2016- 8214217-1
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Mishale Mistry, Pharm.D., MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Esbriet, based the revised strength. The proposed proprietary name, Esbriet, was found acceptable under NDA 208780 on August 9, 2016.¹ We previously reviewed the product with strengths of 267 mg, 537 mg and 801 mg. During review of the application, Genentech decided to launch only the 267 mg and 801 mg strengths, based on the results of a survey conducted with idiopathic pulmonary fibrosis patients. The study concluded that only a limited number of patients favored taking the 534 mg dose strength over the 267 mg dose strength, noting the 534 mg dose strength holds little to no appeal over taking two 267 mg dose strength.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in strength. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 9, 2016, search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable from a promotional and safety perspective.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at (240) 402-2684.

¹[Abraham, S]. Proprietary Name Review for [Esbriet (NDA 208780)]. Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); [2016 August 9]. Panorama No. [2016-8214217].

4 REFERENCES

1. USAN Stems (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

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/s/

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09/14/2016

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PROPRIETARY NAME REVIEW

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Date of This Review:	August 9, 2016
Application Type and Number:	NDA 208780
Product Name and Strengths:	Esbriet (pirfenidone) film-coated tablets 267 mg, 534 mg and 801 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Genentech
Panorama #:	2016- 8214217
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Mishale Mistry, Pharm.D., MPH
DMEPA Deputy Director:	Lubna Merchant, M.S., Pharm.D.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Esbriet, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study.

1.1 REGULATORY HISTORY

Esbriet (pirfenidone) capsules were approved on October 15, 2014, under NDA 22535. The Applicant submitted the name, Esbriet, for a new dosage form, film-coated tablets, under review for NDA 208780 on March 29, 2016.

The following product information is provided in the March 29, 2016, proprietary name submission and proposed Prescribing Information.

Table 1. Relevant Product Information for Esbriet										
Product	Esbriet (NDA 208780)	Esbriet (NDA 22535)								
Initial Approval Date	Currently under review.	October 15, 2014								
Active Ingredient	Pirfenidone									
Indication	Treatment of idiopathic pulmonary fibrosis (IPF)									
Route of Administration	Oral									
Dosage Form:	Film-coated tablets	Capsules								
Strength:	267 mg, 534 mg, 801 mg	267 mg								
Dose and Frequency	Recommended dosage: 801 mg three times daily taken with food. Upon initiation of treatment, the daily dosage should be titrated to the full dosage 2,403 mg/day over a 14-day period as follows: <table border="1" data-bbox="500 1373 1370 1692"> <thead> <tr> <th>Treatment days</th> <th>Dosage</th> </tr> </thead> <tbody> <tr> <td>Days 1 through 7</td> <td>267 mg administered three times a day with meals (801 mg/day)</td> </tr> <tr> <td>Days 8 through 14</td> <td>534 mg administered three times a day with meals (1,602 mg/day)</td> </tr> <tr> <td>Days 15 onward</td> <td>801 mg administered three times a day with meals (2,403 mg/day)</td> </tr> </tbody> </table>		Treatment days	Dosage	Days 1 through 7	267 mg administered three times a day with meals (801 mg/day)	Days 8 through 14	534 mg administered three times a day with meals (1,602 mg/day)	Days 15 onward	801 mg administered three times a day with meals (2,403 mg/day)
Treatment days	Dosage									
Days 1 through 7	267 mg administered three times a day with meals (801 mg/day)									
Days 8 through 14	534 mg administered three times a day with meals (1,602 mg/day)									
Days 15 onward	801 mg administered three times a day with meals (2,403 mg/day)									
How Supplied:	Film-coated tablets are oval, biconvex, debossed with "PFD", containing 267 mg (yellow), 534	White hard gelatin capsules contain 267 mg of pirfenidone. The cap of the capsule is printed								

	<p>mg (b) (4), and 801 mg (brown) pirfenidone. The film-coated tablets are supplied in bottles.</p> <ul style="list-style-type: none"> • NDC 50242-122-05, carton containing 3 bottles, each with 90 267 mg tablets (270 tablets total) with a child-resistant closure • (b) (4) • NDC 50242-123-01, carton containing 1 bottle with 90 801 mg tablets, with a child-resistant closure 	<p>with “PFD 267 mg” in brown ink. The capsule is supplied either in a bottle, a 14-day titration blister pack or a 4-week maintenance blister pack.</p> <ul style="list-style-type: none"> • NDC 50242-121-01, bottle for a 30-day supply containing 270 capsules and closed with a child-resistant closure • NDC 50242-121-02, 14-day titration blister pack, carton containing a total of 63 capsules in two blister cards – a Week 1 blister card containing 21 capsules (1 capsule per blister well) and a Week 2 blister card containing 42 capsules (2 capsules per blister well) • NDC 50242-121-03, 4-week maintenance blister pack, carton containing a total of 252 capsules in four blister cards each with 63 capsules (3 capsules per blister well)
<p>Storage:</p>	<p>Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) (see USP Controlled Room Temperature). Keep the bottle tightly closed. Do not use if the seal over the bottle opening is broken or missing.</p>	

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. DMEPA and Division of Pulmonary, Allergy,

and Rheumatology Products (DPARP) concurred with the findings of OPDP’s assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Esbriet, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A for a description of FAERS database) for name confusion errors involving the capsule formulation of Esbriet. This search did not yield any relevant cases of name confusion with Esbriet.

Table 2. FAERS Search Strategy	
Date	July 25, 2016
Drug Name(Product Name)	Esbriet (Pirfenidone)
MedDRA Event Search	DMEPA Official Proprietary Name Review Search Terms Event List: Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Time/Date Limits	October 1, 2014 to July 1, 2016

¹USAN stem search conducted on July 26, 2016

2.2.4 Multiple Dosage Forms Under a Single Proprietary Name

The Applicant is proposing a new dosage form of Esbriet, film-coated tablets, in their submission of NDA 208780. The Applicant proposes 267 mg, 534 mg, and 801 mg strengths for the film-coated tablets; Esbriet is currently available as 267 mg capsules.

We note that the currently approved Esbriet dosage form (capsules) shares the same active ingredient, indication, route of administration, dose, and frequency. The two dosage forms are both available in a strength of 267 mg. However, the proposed film-coated tablets will also be available in (b) (4) 801 mg strengths. Given the overlapping strength, we consulted the review team with regard to whether the dosage forms are interchangeable. Per the Office of Pharmaceutical Quality (OPQ) reviewer, the 267 mg film-coated tablets and capsules (b) (4)

(b) (4)
Per the clinical reviewer, the film-coated tablets and capsules are interchangeable and switching between them has no clinical significance. It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name within a single package insert. In this case, we determine that the differences in strengths and dosage form can be managed via labeling.

Moreover, we have not retrieved any relevant medication errors involving the proprietary name Esbriet. Therefore, we find the Applicant's proposal to market the proposed product with the proprietary name Esbriet acceptable.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 14, 2016 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on August 1, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on August 9, 2016, they stated no additional concerns with the proposed proprietary name, Esbriet.

3.0 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Michael Sinks, OSE project manager, at (240) 402-2684.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Esbriet, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your March 29, 2016, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES AND DATABASE DESCRIPTION.

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

2. **FDA Adverse Event Reporting System (FAERS)**

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

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/s/

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