CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761044Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	March 7, 2016
Application Type and Number:	BLA 761044
Product Name and Strength:	Stelara (ustekinumab) injection, for intravenous infusion 130 mg/26 mL (5 mg/mL)
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Janssen Biotech, Inc.
Panorama #:	2015-2268009
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Mishale Mistry, Pharm.D., MPH
DMEPA Deputy Director:	Lubna Merchant, M.S., Pharm.D.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Stelara, 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

Stelara (ustekinumab) injection, for subcutaneous use, was approved on September 15, 2009, under BLA 125261. The Applicant submitted the name, Stelara, for a new dosage form, injection for intravenous infusion, under review for BLA 761044 on December 16, 2015.

The following product information is provided in the December 16, 2015 proprietary name submission and proposed Prescribing Information.

Table 1. Relevant Product Information for Stelara

Product	**Stelara (BLA 761044)**	**Stelara (BLA 125261)**
Initial Approval Date	Currently under review.	September 15, 2009
Active Ingredient	Ustekinumab	Ustekinumab
Indication	Treatment of adult patients (18 years or older) with moderate to severely active Crohn's Disease (CD) * who have: • Failed or were intolerant to immunomodulators or corticosteroids, but never failed anti-TNFα treatment or • Failed or were intolerant to one or more anti-TNFα treatment	• Treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy • Treatment of adult patients (18 years or older) with active psoriatic arthritis (PsA), alone or in combination with methotrexate
Route of	Intravenous*	Subcutaneous

* Note: new intravenous formulation is intended only for use as *induction* therapy in CD.

Administration		
Dosage Form:	Injection	
Strength:	130 mg/26 mL (5 mg/mL)	45 mg/0.5 mL 90 mg/mL
Dose and Frequency	Crohn's Disease (initial dose):* A single intravenous infusion dose using weight-based tiers (approximately 6 mg/kg). Body weight of patient at time of dosing: • ≤ 55 kg: dose of 260 mg • > 55 kg to ≤ 85 kg: dose of 390 mg • ≥ 85 kg: dose of 520 mg	Psoriasis: • For patients weighing ≤100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. Psoriatic Arthritis: • The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. Crohn's Disease (maintenance dose): • A subcutaneous 90 mg dose 8 weeks after the initial IV dose, then every 8

* Note: new intravenous formulation is intended only for use as *induction* therapy in CD.

		weeks thereafter. (b) (4) [redacted]
How Supplied:	Single-use vials containing 130 mg ustekinumab for intravenous use.	Single-use prefilled syringes or single-use vials containing 45 mg or 90 mg of ustekinumab. Each prefilled syringe is equipped with a needle safety guard.
Storage:	Vials and prefilled syringes must be refrigerated at 2ºC to 8ºC (36ºF to 46ºF). Store vials upright. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. Does not contain a preservative; discard any unused portion.	

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 the Division of Gastroenterology and Inborn Error Products (DGIEP) 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 name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Stelara, 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 subcutaneous injection formulation of Stelara. This search did not yield any cases of name confusion with Stelara.

Table 2. FAERS Search Strategy	
Date	January 25, 2016
Drug Name(Product Name)	Stelara (Ustekinumab)
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	January 1, 2014 to January 1, 2016

2.2.4 Multiple Dosage Forms Under a Single Proprietary Name

The Applicant is proposing a new indication of Stelara for the treatment of adult patients with moderately to severely active Crohn's Disease (CD) in their submission of BLA 761044. Within this BLA, the Applicant is also proposing a formulation of Stelara, a 130 mg/26 mL (5 mg/mL) intravenous solution for infusion, in a single-use vial. This new formulation is intended for use only as induction therapy in CD.

We note that the currently approved Stelara formulation (for subcutaneous injection) shares the same active ingredient and same dosage form. The two formulations differ in

[1]USAN stem search conducted on January 21, 2016

some characteristics, including indication, strength, and route of administration. It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. Differences in strengths and route of administration can be managed via labeling.

The Applicant states that they have incorporated visual differentiators in the carton labeling and vial label for the proposed 130 mg/26 mL presentation. In addition to the difference in the sizes of the carton and vial between the proposed intravenous formulation and currently approved subcutaneous formulation, the Applicant intends to distribute the 130 mg/26 mL vial presentation directly to physicians, infusion centers, and hospital pharmacies, thus mitigating any confusion at the patient level.

Moreover, we have not retrieved any medication errors involving the proprietary name Stelara. Therefore, given the precedent for using this naming convention, and the absence of any medication errors involving the proprietary name, we find the Applicant's proposal to market the proposed product with the proprietary name Stelara acceptable.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 14, 2016 e-mail, the Division of the Division of Gastroenterology and Inborn Errors Products (DGIEP) 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 Gastroenterology and Inborn Errors Products (DGIEP) via e-mail on February 29, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on March 7, 2016, they stated no additional concerns with the proposed proprietary name, Stelara.

3.0 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 16, 2015, 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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SHERLY ABRAHAM
03/10/2016

MISHALE P MISTRY
03/10/2016

LUBNA A MERCHANT
03/10/2016