



BLA 125261/S-129

**SUPPLEMENT APPROVAL**

Janssen Biotech, Inc.  
Attention: Donna Kipphorn  
Associate Director, Global Regulatory Affairs, Immunology  
Welsh & McKean Roads, PO Box 776  
Spring House, PA 19477

Dear Ms. Kipphorn:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received December 16, 2016, submitted under section 351(a) of the Public Health Service Act for Stelara<sup>®</sup> (ustekinumab).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment, dated December 16, 2016.

This Prior Approval supplemental biologics application provides for a request for release from the REMS.

**APPROVAL & LABELING**

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

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the prescribing information and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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.

### **RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

The REMS for Stelara (ustekinumab) was originally approved on September 25, 2009, and the most recent modification was approved on May 2, 2012. The REMS consists a communication plan, and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of a request to be released from the REMS.

Therefore, because the communication plan and assessments are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Stelara® (ustekinumab).

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Dawn Williams, Regulatory Project Manager, at (301) 796-5376.

Sincerely,

*{See appended electronic signature page}*

Tatiana Oussova, MD, MPH  
Deputy Director for Safety  
Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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TATIANA OUSSOVA  
02/15/2017