DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125261/063

SUPPLEMENT APPROVAL
REMOVE REMS ELEMENT

Janssen Biotech, Inc.
Attention: Joseph A. Lallier, MS, MBA
Associate Director, North American Regulatory Liaison
1400 McKean Road
P.O. Box 776
Spring House, PA 19477

Dear Mr. Lallier:

Please refer to your Supplemental Biologics License Application (sBLA), dated November 16, 2011, received November 16, 2011, submitted under section 351 of the Public Health Service Act for Stelara® (ustekinumab) Injection 45 mg/0.5 mL and 90 mg/mL Prefilled Syringes.

We acknowledge receipt of your amendments dated December 19, 2011; February 8, March 14, April 2 and 3, 2012; and your risk evaluation and mitigation strategy (REMS) assessment dated March 25, 2011.

This supplemental new drug application proposes to eliminate the Medication Guide as an element of the approved Stelara® REMS.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Stelara® was originally approved on September 25, 2009, and the most recent REMS modification was approved on August 19, 2011. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of eliminating the requirement for the Medication Guide as an element of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of the Stelara® outweigh the risks.

Therefore, we agree with your proposal, and a Medication Guide is no longer required as part of the REMS for Stelara®.

Your proposed modified REMS, submitted on March 14, 2012, and appended to this letter, is approved.

The modified REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

We remind you that the Medication Guide will continue to be part of the approved labeling for Stelara® in accordance with 21 CFR 208.

The timetable for submission of assessments of the REMS will remain the same as that approved on September 25, 2009.

The revised REMS assessment plan should include, but is not limited to the following:

1. Evaluations of dermatologists/healthcare providers' understanding of the risks of Stelara® (ustekinumab), including evaluations of the following:
    a. Precribers' understanding of the risks of Stelara® (ustekinumab) including the risks of serious infection, RPLS, and malignancy and how to select patients who are appropriate for treatment

2. A summary of all reported serious infections, RPLS, and malignancies with analysis of adverse event reporting by prescriber type (e.g., dermatologist, nurse, internist, oncologist), when available

3. Based on the information submitted, an assessment and conclusion of whether the REMS is meeting its goals, and whether modifications to the REMS are needed.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

BLA 125261 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

BLA 125261 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125261
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125261
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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 Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

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

ENCLOSURES:
REMS

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

/s/

TATIANA OUSSOVA
05/02/2012