DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125288/S-072

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Dana Leeds, Ph.D.
US Regulatory Liaison,
P.O. Box 4000 (Mail Stop: D22-08)
Princeton, NJ 08543-4000

Dear Dr. Leeds:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received on March 29, 2017, submitted under section 351(a) of the Public Health Service Act for Nulojix (belatacept).

This Prior Approval supplemental biologics application provides for proposed modification to eliminate the requirement for the approved REMS for Nulojix (belatacept). This supplement is in response to our February 2, 2017, REMS Modification Notification letter.

APPROVAL & LABELING

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

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, 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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Nulojix (belatacept) was originally approved on June 15, 2011, and there were no modification since approval. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

As communicated in our REMS Modification Notification letter dated February 2, 2017, we determined that the communication plan and the Medication Guide as an element of the REMS were no longer necessary to ensure the benefits outweigh the risks and that the approved REMS had to be modified to minimize the burden on the healthcare delivery system of complying with the REMS.

We have determined that maintaining the Medication Guide as part of labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208. Therefore, it is no longer necessary to include the Medication Guide as an element of the REMS to ensure that the benefits of Nulojix (belatacept) outweigh its risks. The Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

Because the communication plan has been completed and the assessment demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, because the Medication Guide and the communication plan are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Nulojix (belatacept).

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 Ms. June Germain, Safety Regulatory Project Manager, at (301) 796-4024.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD, MPH
Deputy Director for Safety
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

OZLEM A BELEN
05/09/2017