NDA 50722/S-045 and S-046
NDA 50723/S-045 and S-046
NDA 50758/S-042 and S-043
NDA 50759/S-050 and S-051

**SUPPLEMENT APPROVAL**

Roche Palo Alto LLC
c/o Genentech Inc.
1 DNA Way
South San Francisco, CA 94080-4990

Attention: Elizabeth Wishart
Regulatory Agent on behalf of Roche

Dear Ms. Wishart:

Please refer to your supplemental new drug applications (sNDAs) and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

| NDA Number | Supplement Number | Drug Name | Submitted and Received |
|---|---|---|---|
| 50722 | 045 | CellCept (mycophenolate mofetil) Capsules, 250 mg | August 19, 2020 |
| 50723 | 045 | CellCept (mycophenolate mofetil) Tablets, 500 mg | August 19, 2020 |
| 50758 | 042 | CellCept (mycophenolate mofetil hydrochloride) Intravenous | August 19, 2020 |
| 50759 | 050 | CellCept (mycophenolate mofetil) Oral suspension | August 19, 2020 |

And

| NDA Number | Supplement Number | Drug Name | Submitted and Received |
|---|---|---|---|
| 50722 | 046 | CellCept (mycophenolate mofetil) Capsules, 250 mg | January 15, 2021 |
| 50723 | 046 | CellCept (mycophenolate mofetil) Tablets, 500 mg | January 15, 2021 |
| 50758 | 043 | CellCept (mycophenolate mofetil hydrochloride) Intravenous | January 15, 2021 |
| 50759 | 051 | CellCept (mycophenolate mofetil) Oral suspension | January 15, 2021 |

These Prior Approval sNDAs provides for:

1. Revisions to update **WARNINGS and PRECAUTIONS** subsection **5.7** to include the addition of Acute Inflammatory Syndrome as a serious adverse reaction (submitted August 19, 2020), and

2. Revisions to update the **WARNINGS and PRECAUTIONS** subsection **5.3** to include a new warning regarding the increased risk of COVID-19 infection (submitted January 15, 2021).

## APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.
Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

## REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 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.

## REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Christine Ford, Regulatory Project Manager, at 301-796-3420.

Sincerely,

*{See appended electronic signature page}*

Ozlem Belen, MD, MPH
Deputy Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
- Prescribing Information
- Medication Guide

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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