NDA 050722/S-050
NDA 050723/S-050
NDA 050758/S-048
NDA 050759/S-055

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 pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Supplement Number	Drug Name	Dated and Received
050722	050	CellCept (mycophenolate mofetil) Capsules, 250 mg	January 27, 2022
050723	050	CellCept (mycophenolate mofetil) Tablets, 500 mg	January 27, 2022
050758	048	CellCept (mycophenolate mofetil hydrochloride) Intravenous	January 27, 2022
050759	055	CellCept (mycophenolate mofetil) Oral suspension	January 27, 2022

These Prior Approval supplemental NDAs provide for:

- Revisions to the US Prescribing Information, subsection 12.1 with updated information about the mechanism of action of mycophenolate mofetil, and
- Revision to the Instructions for Use to avoid damage to the oral dispenser.

APPROVAL & LABELING

We have completed our review of these applications, as amended (final labeling amendment dated August 2, 2022). 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, Instructions for Use, 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).

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 these supplemental applications, 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).

[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.

If you have any questions, call Saharat Patanavanich, Regulatory Project Manager, at (240) 402-0139.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling
- Prescribing Information
- Medication Guide
- Instructions for Use

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.

/s/

OZLEM A BELEN
08/10/2022 11:52:27 AM