NDA 050722/S-054
NDA 050723/S-054
NDA 050758/S-052
NDA 050759/S-061

SUPPLEMENT APPROVAL

Roche Palo Alto LLC
c/o Genentech Inc.
Attention: Elizabeth Wishart
Regulatory Agent on behalf of Roche
1 DNA Way
South San Francisco, CA 94080-4990

Dear Elizabeth Wishart:

Please refer to your supplemental new drug applications (sNDAs) 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	054	CellCept (mycophenolate mofetil) capsules, 250 mg	May 14, 2025
050723	054	CellCept (mycophenolate mofetil) tablets, 500 mg	May 14, 2025
050758	052	CellCept Intravenous (mycophenolate mofetil hydrochloride)	May 14, 2025
050759	061	CellCept Oral Suspension (mycophenolate mofetil)	May 14, 2025

We also refer to our letter dated April 15, 2025, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we have determined should be included in the labeling for mycophenolate products. This information pertains to the risk of serious hypersensitivity reactions, including anaphylaxis and angioedema.

These supplemental new drug applications provide for revisions to the US Prescribing Information for CellCept, consistent with our April 15, 2025, safety labeling change notification letter.

APPROVAL & LABELING

We have completed our review of these applications. 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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.

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 supplemental application, you are exempt from this requirement.

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

PROMOTIONAL MATERIALS

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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, contact June Germain, Associate Director for Labeling, at june.germain@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Hyon Kwon, PharmD, MPH
Deputy Director for Safety
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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.

/s/

HYON J KWON
06/27/2025 02:22:15 PM