



NDA 50722/S038
NDA 50723/S038
NDA 50758/S035
NDA 50759/S043

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 Dr. Wishart:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received August 29, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) as follows:

NDA Number	Supplement	Drug Name
50722	038	CellCept (mycophenolate mofetil) capsules, for oral use, 250 mg
50723	038	CellCept (mycophenolate mofetil) tables, for oral use, 500 mg
50758	035	CellCept Intravenous (mycophenolate mofetil) for injection, for intravenous use
50759	043	CellCept Oral Suspension (mycophenolate mofetil), for oral suspension

These “Changes Being Effected” supplemental new drug applications provide for:

- a. The addition of a new warning in Section 5 (5.12 Concomitant Medications), regarding checking MPA concentrations when starting or discontinuing concomitant medications that may affect MPA exposure.
- b. The addition of a new warning in Section 5 (5.13 Impairment of Ability to Drive or Operate Machinery)

- c. The conversion of the adverse event (AE) tables (tables 3 and 4) in Section 6.0 to adverse drug reaction (ADR) tables by removing the AEs with no plausible association with CellCept administration

We also note that these supplements propose numerous editorial changes.

APPROVAL & LABELING

We have completed our review of these supplemental application, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the labeling submitted on February 11, 2019.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling text for the Prescribing Information, 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 titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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 these supplemental applications, as well as annual reportable changes. To facilitate review of your submissions, 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 numbers and annual report dates.

REPORTING REQUIREMENTS

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

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If you have any questions, call Judit Milstein, Chief, Project Management Staff at 301-796-0763.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD MPH
Acting Director
Division of Transplant and Ophthalmology Product
Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE: Prescribing Information

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
02/27/2019 03:56:38 PM