

NDA 50722/S040
 NDA 50723/S041
 NDA 50758/S037
 NDA 50759/S045

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) and their amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) as follows:

NDA/supplement number	Product name	Submission/receipt date
50758/S037	CellCept Intravenous (mycophenolate mofetil) for injection, for intravenous use	June 14, 2019
50759/S045	CellCept Oral Suspension (mycophenolate mofetil) for oral suspension	October 4, 2019
50722/S040	CellCept (mycophenolate mofetil) capsules, for oral use, 250 mg	November 12, 2019
50723/S041	CellCept (mycophenolate mofetil) tablets, for oral use, 500 mg	November 12, 2019

These Prior Approval supplemental new drug applications provide for:

1. Revisions to the Package Insert, Medication Guide and Carton and Container labels to comply with the Guidance for Industry “Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose and Single-Patient-Use Containers for Human Use.”
2. Revisions to update the strength and dosage form terminology across different sections of the Package Insert.

3. Revisions to the 5.7 Immunizations section of the Package Insert (added text is shown as underlined).

5.7 Immunizations

During treatment with CELLCEPT, the use of live attenuated vaccines should be avoided (e.g., intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella and TY21a typhoid vaccines) and patients should be advised that vaccinations may be less effective. Advise patients to discuss with the physician before seeking any immunizations.

These supplements also provide for numerous editorial changes all throughout the labeling.

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 Package Insert 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

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>.

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).

CARTON AND CONTAINER LABELING

Submit final printed Carton and Container labeling that is identical to the enclosed Carton and Container labeling as soon as it is available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 50758/S037.**” Approval of this submission by FDA is not required before the labeling is used.

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 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 Products
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
- Carton and Container Labeling

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
12/13/2019 02:17:34 PM