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APPLICATION NUMBER: : 050759

MEDICAL REVIEW(S)

MEMO

Date: September 29, 1998

From: Joyce Korvick, M.D., reviewing Medical Officer /S/ 9/29/98

To: Mark Goldberger, M.D., Division Director: HFD-590

Through: Marc Cavaillé-Coll, M.D., Team Leader

Re: NDA 50-759
CellCept® Oral Suspension
(mycophenolate mofetil for oral suspension)
Proposal for Final Labeling
Dated: Sept 22, 1998

Medical Officer Comments:

Final labeling for the new oral suspension of CellCept® has been discussed with the Chemistry and Biopharmaceutics FDA reviewers. There was no clinical efficacy submission to this label. The suspension was found to be bioequivalent with the currently approved formulations. The amendments to the original CellCept® label describe the new product and the bioequivalence, and do not change the efficacy section or the safety section of the label.

Medical Officer Recommendation:

Recommend approval of proposed changes to package insert for CellCept® regarding oral suspension submitted September 22, 1998.

Concurrence:
Mark Goldberger, Division Director: HFD-590
Marc Cavaillé-Coll; Team Leader: HFD-590 /S/ 9.29.98

CC:
HFD-590 Division Files
NDA files # 50-759
HFD-590/Chemistry/Seggel, M.
HFD-590/TL/Cavaillé-Coll,M.
HFD-590/Biopharm/Kumi, K.