

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-722/S-006

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE

MEMORANDUM OF TELEPHONE CONVERSATION--HFD-590

DATE: April 3, 2000
NDA: 50-722/S-006
PRODUCT: CellCept
APPLICANT: Hoffmann-La Roche Inc.
BETWEEN: Debra Iorio, Program Manager
973-562-3550
and: Mark Seggel, Review Chemist, HFD-590 *MS*

Background: Supplement SCS-006 provides for a new strain of microorganism to be used in the fermentation of the _____ which is used to produce the active ingredient, mycophenolate mofetil (MMF), in the CellCept product line.

Discussion: It was noted that some comparative analytical data were already provided in the supplement. However, additional data supporting the proposed change in microorganism strain were requested. First, more detailed or complete comparative _____ profiles for current strain and new strain _____ were requested. Known _____ should be identified by



file: mpa040300.mtc

**APPEARS THIS WAY
ON ORIGINAL**