

Mycophenolate shared system

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Current application holders of the shared system REMS

Product name	Application number	Application holder
Myfortic	NDA 050791	Novartis Pharmaceuticals Corporation
CellCept	NDA 050759	Genentech
CellCept	NDA 050758	Genentech
CellCept	NDA 050723	Genentech
CellCept	NDA 050722	Genentech
mycophenolate mofetil	ANDA 203005	Alkem Laboratories, Ltd.
mycophenolate mofetil	ANDA 202720	Teva Pharmaceuticals USA
mycophenolate mofetil	ANDA 200197	Alkem Laboratories, Ltd.
mycophenolic acid	ANDA 091558	Apotex Inc
mycophenolic acid	ANDA 091248	Mylan Pharmaceuticals
mycophenolate mofetil	ANDA 090762	Cadista Pharmaceuticals
mycophenolate mofetil	ANDA 090661	Cadista Pharmaceuticals
mycophenolate mofetil	ANDA 090606	Vintage Pharmaceuticals, LLC
mycophenolate mofetil	ANDA 090499	Apotex Corporation

mycophenolate mofetil	ANDA 090456	Strides Arcolab, Ltd.
mycophenolate mofetil	ANDA 090419	Apotex Corporation
mycophenolate mofetil	ANDA 090253	Accord Heakthcare Inc
mycophenolate mofetil	ANDA 090111	Vintage Pharmaceuticals,LLC
mycophenolate mofetil	ANDA 090055	Strides Arcolab, Ltd.
mycophenolate mofetil	ANDA 065521	Mylan Pharmaceuticals Inc
mycophenolate mofetil	ANDA 065520	Mylan Pharmaceuticals Inc
mycophenolate mofetil	ANDA 065491	Teva Pharmaceuticals, USA
mycophenolate mofetil	ANDA 065457	Teva Pharmaceuticals, USA
mycophenolate mofetil	ANDA 065416	Accord Heakthcare Inc
mycophenolate mofetil	ANDA 065413	Roxane Laboratories, Inc
mycophenolate mofetil	ANDA 065410	Roxane Laboratories, Inc
mycophenolate mofetil	ANDA 091249	Alkem Laboratories, Ltd.
mycophenolate mofetil	ANDA 065451	Sandoz, Inc
mycophenolate mofetil	ANDA 065379	Sandoz, Inc

Number of total products= 29