Drugs@FDA: FDA Approved Drug Products

Home | Previous Page

Abbreviated New Drug Application (ANDA): 065451
Company: SANDOZ

- Other Important Information from FDA
- REMS

Products on ANDA 065451

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL	500MG	TABLET;ORAL	Prescription	AB	No	No

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 065451

Original Approvals or Tentative Approvals

CSV | Excel | Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
10/15/2008	ORIG-1	Approval				Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements

CSV | Excel | Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/13/2015	SUPPL-18	REMS-Proposal		Label is not available on this site.
11/09/2015	SUPPL-19	Labeling-Medication Guide, Labeling-Package Insert		Label is not available on this site.
09/27/2013	SUPPL-16	Labeling-Medication Guide		Label is not available on this site.
10/12/2012	SUPPL-10	Labeling-Medication Guide, Labeling-Package Insert		Label is not available on this site.
09/25/2012	SUPPL-9	REMS-Proposal		Label is not available on this site.
02/02/2010	SUPPL-3	Labeling-Package Insert		Label is not available on this site.
03/24/2009	SUPPL-1	Labeling		Label is not available on this site.

Showing 1 to 7 of 7 entries

Therapeutic Equivalents for ANDA 065451

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Contact FDA