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New Drug Application (NDA): 050790

Company: ALLERGAN

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Products on NDA 050790



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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
RESTASIS MULTIDOSE	CYCLOSPORINE	0.05%	EMULSION;OPHTHALMIC	Prescription	Yes	None
RESTASIS	CYCLOSPORINE	0.05%	EMULSION;OPHTHALMIC	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 050790



Original Approvals or Tentative Approvals

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MYLAN - EXHIBIT 1064

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, R
12/23/2002	ORIG-1	Approval	Type 3 - New Dosage Form	PRIORITY	Label (PDF) (https://www.acce) Letter (PDF) (https://www.acce) Review (https://www.accessda)

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Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, L Patient Package I
10/27/2016	SUPPL-25	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/lab)
10/27/2016	SUPPL-24	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/lab)
01/16/2014	SUPPL-22	Manufacturing (CMC)	
12/05/2013	SUPPL-23	Manufacturing (CMC)	
05/31/2013	SUPPL-21	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatf)
01/16/2013	SUPPL-19	Manufacturing (CMC)	
12/03/2012	SUPPL-20	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap)

Action Date	Submission	Submission Classification	Letters, Reviews, L Patient Package I
12/27/2007	SUPPL-13	Labeling- Container/Carton Labels	
10/01/2003	SUPPL-4	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap)
10/01/2003	SUPPL-3	Manufacturing (CMC) -Packaging	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap)
09/16/2003	SUPPL-1	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/lab) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap)
09/12/2003	SUPPL-2	Manufacturing (CMC)	Review (https://www.accessdata.fda.gov/drugsatfda_docs/nd)

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Labels for NDA 050790

