Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 050790
Company: ALLERGAN

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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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Re
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

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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/drugsat**
01/16/2013	SUPPL-19	Manufacturing (CMC)	
12/03/2012	SUPPL-20	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsat 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