Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020114
Company: MYLAN SPECIALITY LP

Products on NDA 020114

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Cod
ASTELIN	AZELASTINE HYDROCHLORIDE	EQ 0.125MG BASE/SPRAY	SPRAY, METERED;NASAL	Prescription	AB

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020114

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient P
11/01/1996	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	**Review (PDF) (https://www.accessdata.f**

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
09/06/2018	SUPPL-28	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020114s0**
10/23/2014	SUPPL-26	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020114s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/0201**
03/13/2014	SUPPL-25	Manufacturing (CMC)	
01/20/2012	SUPPL-23	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020114s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/0201**
08/10/2007	SUPPL-17	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/0201**
02/17/2006	SUPPL-14	Efficacy-New Dosing Regimen	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
06/27/2001	SUPPL-7	Manufacturing (CMC)-Control	
10/13/2000	SUPPL-3	Manufacturing (CMC)	
09/15/2000	SUPPL-6	Efficacy-New Patient Population	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/2011** **Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20114S00**
05/30/2000	SUPPL-5	Efficacy-New Indication	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/2011**
02/16/1999	SUPPL-2	Labeling	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
09/29/1997	SUPPL-1	Labeling	

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Labels for NDA 020114

Therapeutic Equivalents for NDA 020114