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New Drug Application (NDA): 020114

Company: MYLAN SPECIALITY LP

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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

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.fda.gov/drugsatfda_docs/nda/020114orig1s1/nda.pdf)

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Supplements

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/2014/020114s0)
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/2012/020114s0)
08/10/2007	SUPPL-17	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/020114s0)
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/2000/20114 Review https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20114S006
05/30/2000	SUPPL-5	Efficacy-New Indication	Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20114
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