

# Drugs@FDA: FDA-Approved Drugs

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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

Showing 1 to 1 of 1 entries

**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	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/020114orig1s1/nda020114orig1s1.pdf">Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/020114orig1s1/nda020114orig1s1.pdf)</a>

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**Supplements**

<b>Action Date</b>	<b>Submission</b>	<b>Supplement Categories or Approval Type</b>	<b>Letters, Reviews, Labels, Patient Package Insert</b>
09/06/2018	SUPPL-28	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020114s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020114s0</a> )
10/23/2014	SUPPL-26	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020114s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020114s0</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/020114s0">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/020114s0</a> )
03/13/2014	SUPPL-25	Manufacturing (CMC)	
01/20/2012	SUPPL-23	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020114s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020114s0</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/020114s0">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/020114s0</a> )
08/10/2007	SUPPL-17	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/020114s0">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/020114s0</a> )
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	<b>Letter (PDF)</b> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20114">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20114</a> <b>Review</b> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20114S006">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20114S006</a>
05/30/2000	SUPPL-5	Efficacy-New Indication	<b>Letter (PDF)</b> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20114">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20114</a>
02/16/1999	SUPPL-2	Labeling	

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

Showing 1 to 12 of 12 entries

**[Labels for NDA 020114](#)**

**[Therapeutic Equivalents for NDA 020114](#)**