

# Drugs@FDA: FDA-Approved Drugs

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA-APPROVED DRUGS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet/?text=Drugs@FDA: FDA-Approved Drugs&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process)

 [LINKEDIN \(HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS&TITLE=DRUGS@FDA: FDA-APPROVED DRUGS&SOURCE=FDA\)](https://www.linkedin.com/sharearticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process&title=Drugs@FDA: FDA-Approved Drugs&source=fda)

 [PIN IT \(HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS&DESCRIPTION=DRUGS@FDA: FDA-APPROVED DRUGS\)](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process&description=Drugs@FDA: FDA-Approved Drugs)


 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA-APPROVED DRUGS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=Drugs@FDA: FDA-Approved Drugs&body=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=basicsearch.process)

 PRINT

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 020114

Company: MYLAN SPECIALITY LP

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020114\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process%26varapplno=020114)

## Products on NDA 020114

CSV

Excel

Print

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**

CSV Excel Print

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) ( <a href="https://www.accessdata.f">https://www.accessdata.f</a>

Showing 1 to 1 of 1 entries

**Supplements**

CSV Excel Print

<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](#)**