Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 202236
Company: MYLAN SPECIALITY LP

- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202236Orig1s000SumR.pdf)

Products on NDA 202236

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	T C
DYMISTA	AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE	EQ 0.125MG BASE/SPRAY;0.05MG/SPRAY	SPRAY, METERED;NASAL	Prescription	AB

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 202236

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Pac
05/01/2012	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.g Letter (PDF) (https://www.accessdata.fda.g Review (https://www.accessdata.fda.gov/d Summary Review (PDF) (https://www.acce

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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-10	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202236s010 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/202236**
01/06/2017	SUPPL-9	Manufacturing (CMC)	
02/20/2015	SUPPL-8	Efficacy-New Patient Population	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202236s008 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/202236**
10/29/2014	SUPPL-7	Manufacturing (CMC)	
06/02/2014	SUPPL-5	Manufacturing (CMC)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
01/21/2014	SUPPL-4	Manufacturing (CMC)	
03/26/2013	SUPPL-3	Manufacturing (CMC)	
11/19/2012	SUPPL-2	Manufacturing (CMC)	
08/10/2012	SUPPL-1	Labeling-Container/Carton Labels, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202236s00 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202236**

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Labels for NDA 202236

Therapeutic Equivalents for NDA 202236