Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 018148
Company: IVAX RES

Products on NDA 018148

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Co
NASALIDE	FLUNISOLIDE	0.025MG/SPRAY	SPRAY, METERED;NASAL	Discontinued	None

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 018148

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels Patient Package Insert
09/24/1981	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY	

Showing 1 to 1 of 1 entries

Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/23/2002	SUPPL-37	Manufacturing (CMC)-Control	
05/09/2002	SUPPL-35	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/**
05/09/2002	SUPPL-30	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/**
09/13/2000	SUPPL-33	Manufacturing (CMC)	
06/29/2000	SUPPL-32	Manufacturing (CMC)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
02/25/1999	SUPPL-23	Efficacy-New Dosing Regimen	**Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/18148s**
02/05/1999	SUPPL-29	Manufacturing (CMC)-Control	
04/21/1998	SUPPL-28	Manufacturing (CMC)-Control	
08/02/1996	SUPPL-27	Manufacturing (CMC)	
08/17/1994	SUPPL-24	Manufacturing (CMC)-Control	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/05/1994	SUPPL-25	Manufacturing (CMC)-Control	
08/25/1989	SUPPL-14	Manufacturing (CMC)	
03/07/1989	SUPPL-22	Manufacturing (CMC)-Packaging	
02/08/1989	SUPPL-21	Labeling	
12/23/1987	SUPPL-20	Manufacturing (CMC)-Control	

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