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New Drug Application (NDA): 018148

Company: IVAX RES

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Products on NDA 018148



Exhibit 1110
IPR2017-00807
ARGENTUM

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
NASALIDE	FLUNISOLIDE	0.025MG/SPRAY	SPRAY, METERED;NASAL	Discontinued	None	No	No

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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	Notes
09/24/1981	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY		Label is not available on this site.

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	Note
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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/23/2002	SUPPL-37	Manufacturing (CMC)-Control		Label is not available on this site.
05/09/2002	SUPPL-35	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/18148S030ltr.pdf)	Label is not available on this site.
05/09/2002	SUPPL-30	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/18148S030ltr.pdf)	Label is not available on this site.
09/13/2000	SUPPL-33	Manufacturing (CMC)		Label is not available on this site.
06/29/2000	SUPPL-32	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/25/1999	SUPPL-23	Efficacy-New Dosing Regimen	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/18148s023_nasalide.pdf)	Label is not available on this site.
02/05/1999	SUPPL-29	Manufacturing (CMC)-Control		Label is not available on this site.
04/21/1998	SUPPL-28	Manufacturing (CMC)-Control		Label is not available on this site.
08/02/1996	SUPPL-27	Manufacturing (CMC)		Label is not available on this site.
08/17/1994	SUPPL-24	Manufacturing (CMC)-Control		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/05/1994	SUPPL-25	Manufacturing (CMC)-Control		Label is not available on this site.
08/25/1989	SUPPL-14	Manufacturing (CMC)		Label is not available on this site.
03/07/1989	SUPPL-22	Manufacturing (CMC)-Packaging		Label is not available on this site.
02/08/1989	SUPPL-21	Labeling		Label is not available on this site.
12/23/1987	SUPPL-20	Manufacturing (CMC)-Control		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/19/1986	SUPPL-15	Labeling		Label is not available on this site.
08/19/1986	SUPPL-11	Manufacturing (CMC)-Control		Label is not available on this site.
04/21/1986	SUPPL-7	Manufacturing (CMC)-Formulation		Label is not available on this site.
09/23/1985	SUPPL-12	Labeling		Label is not available on this site.
07/11/1985	SUPPL-13	Labeling		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/21/1985	SUPPL-8	Manufacturing (CMC)-Control		Label is not available on this site.
03/13/1984	SUPPL-10	Labeling		Label is not available on this site.
09/09/1983	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.
09/09/1983	SUPPL-4	Manufacturing (CMC)		Label is not available on this site.
09/09/1983	SUPPL-3	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/09/1983	SUPPL-2	Manufacturing (CMC)		Label is not available on this site.
08/30/1983	SUPPL-1	Labeling		Label is not available on this site.
06/22/1983	SUPPL-6	Labeling		Label is not available on this site.

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