Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 016996
Company: SCHERING

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=016996)

Products on NDA 016996

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
HYPERSTAT	DIAZOXIDE	15MG/ML	INJECTABLE;INJECTION	Discontinued	None	No	No

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 016996

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
01/22/1973	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
03/13/2009	SUPPL-12	Labeling		Label is not available on this site.
11/09/2000	SUPPL-23	Manufacturing (CMC)-Control		Label is not available on this site.
04/29/1999	SUPPL-22	Manufacturing (CMC)		Label is not available on this site.
10/21/1998	SUPPL-21	Manufacturing (CMC)		Label is not available on this site.
06/04/1997	SUPPL-20	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/01/1996	SUPPL-19	Manufacturing (CMC)		Label is not available on this site.
02/05/1990	SUPPL-18	Manufacturing (CMC)		Label is not available on this site.
06/12/1987	SUPPL-17	Manufacturing (CMC)		Label is not available on this site.
10/20/1986	SUPPL-4	Manufacturing (CMC)-Control		Label is not available on this site.
07/23/1986	SUPPL-16	Manufacturing (CMC)-Control		Label is not available on this site.
04/07/1986	SUPPL-15	Manufacturing (CMC)-Control		Label is not available on this site.
09/17/1985	SUPPL-14	Manufacturing (CMC)		Label is not available on this site.
08/21/1984	SUPPL-9	Efficacy		Label is not available on this site.
08/13/1984	SUPPL-13	Manufacturing (CMC)-Control		Label is not available on this site.
01/07/1983	SUPPL-10	Labeling		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/08/1982	SUPPL-11	Labeling		Label is not available on this site.
04/20/1981	SUPPL-6	Efficacy		Label is not available on this site.
01/08/1981	SUPPL-8	Manufacturing (CMC)-Expiration Date		Label is not available on this site.
08/14/1980	SUPPL-7	Manufacturing (CMC)-Formulation		Label is not available on this site.
02/04/1980	SUPPL-5	Labeling		Label is not available on this site.
02/04/1980	SUPPL-3	Labeling		Label is not available on this site.
02/04/1980	SUPPL-2	Labeling		Label is not available on this site.
06/30/1978	SUPPL-1	Labeling		Label is not available on this site.

Showing 1 to 23 of 23 entries