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New Drug Application (NDA): 020444

Company: GLAXOSMITHKLINE LLC

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Products on NDA 020444

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
FLOLAN	EPOPROSTENOL SODIUM	EQ 0.5MG BASE/VIAL	INJECTABLE;INJECTION	Prescription	Yes	AP
FLOLAN	EPOPROSTENOL SODIUM	EQ 1.5MG BASE/VIAL	INJECTABLE;INJECTION	Prescription	Yes	AP

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020444

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
09/20/1995	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY ; Orphan		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
04/17/2015	SUPPL-21	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020444s0)
03/29/2011	SUPPL-18	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020444s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/020444s0)
03/12/2008	SUPPL-16	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020444s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/020444s0)
09/20/2002	SUPPL-10	Manufacturing (CMC)	
06/21/2002	SUPPL-9	Manufacturing (CMC)	
06/21/2002	SUPPL-8	Manufacturing (CMC)-Packaging	

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
04/05/2002	SUPPL-7	Manufacturing (CMC)	
01/17/2002	SUPPL-6	Manufacturing (CMC)	
09/21/2000	SUPPL-5	Labeling	
04/14/2000	SUPPL-3	Efficacy-New Indication	Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20444S03 Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20444 Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20444S003_Flolan.cfm)
11/02/1999	SUPPL-4	Labeling	
11/21/1997	SUPPL-2	Manufacturing (CMC)	
03/18/1996	SUPPL-1	Labeling	

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Labels for NDA 020444

Therapeutic Equivalents for NDA 020444

