Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 022260
Company: ACTELION PHARMS LTD

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Products on NDA 022260

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
VELETRI	EPOPROSTENOL SODIUM	EQ 1.5MG BASE/VIAL	INJECTABLE;INJECTION	Prescription	Yes	None
VELETRI	EPOPROSTENOL SODIUM	EQ 0.5MG BASE/VIAL	INJECTABLE;INJECTION	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022260

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews
06/27/2008	ORIG-1	Approval	Type 5 - New Formulation or New Manufacturer	STANDARD	**Letter (PDF) (https://www.accessdata.fda.gov/ Review (https://www.accessdata.fda.gov/drug Summary Review (PDF) (https://www.accessd**

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Supplements

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Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
07/18/2016	SUPPL-8	Manufacturing (CMC)	
03/03/2015	SUPPL-7	Manufacturing (CMC)	
06/28/2012	SUPPL-5	Manufacturing (CMC)	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022260s0**
03/30/2011	SUPPL-4	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022260s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/02226**
08/23/2010	SUPPL-2	Labeling-Proprietary Name Change	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022260s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/02226**

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Labels for NDA 022260

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