Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 020572
Company: HORIZON PHARMA INC
Drug Name(s):

- BUPHENYL (SODIUM PHENYLBUTYRATE)

Products on NDA 020572

Approval Date(s) and History, Letters, Labels, Reviews for NDA 020572

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	Note
05/13/1996	**ORIG-1**	**Approval**	**Type 3 - New Dosage Form**	**PRIORITY ; Orphan**		**Label not availa on th site.**

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Supplements

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Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	N
10/06/2015	**SUPPL-21**	**Manufacturing (CMC)**		
08/02/2013	**SUPPL-20**	**Manufacturing (CMC)**		
03/31/2009	**SUPPL-16**	**Labeling**	**Label (PDF) (http://www.accessdata.fda.gov /drugsatfda_docs/label /2009/020572s016,020573s015lbl.pdf) Letter (PDF) (http://www.accessdata.fda.gov /drugsatfda_docs/appletter /2009/020572s016,020573s015ltr.pdf)**	
10/09/1998	**SUPPL-2**	**Labeling**		
11/07/1996	**SUPPL-1**	**Manufacturing (CMC)-Control**		

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Labels for NDA 020572

Therapeutic Equivalents for NDA 020572