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New Drug Application (NDA): 020572

Company: HORIZON PHARMA INC

Drug Name(s):

- BUPHENYL (SODIUM PHENYLBUTYRATE)

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Products on NDA 020572

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

Original Approvals or Tentative Approvals

[CSVExcelPrint](#)

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
05/13/1996	ORIG-1	Approval	Type 3 - New Dosage Form	PRIORITY ; Orphan		Label not available on this site.

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Supplements

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Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	Notes
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/appltr/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

