ıgs@FDA: FDA Approved ıg Products

ndex.cfm) | Previous Page

g Application (NDA): 018164
y: ATNAHS PHARMA US

ation Guide
//www.accessdata.fda.gov/drugsatfda_docs/label/2017/017581s113,018123,020067s020lbl.pdf#page=22)

Important Information from FDA
(//www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103420.htm)

cts on NDA 018164

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g he	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
ROX	NAPROXEN SODIUM	EQ 250MG BASE	TABLET;ORAL	Prescription	AB
ROX	NAPROXEN SODIUM	EQ 500MG BASE	TABLET;ORAL	Prescription	AB

ng 1 to 2 of 2 entries

val Date(s) and History, Letters, Labels, Reviews for NDA 018164

al Approvals or Tentative Approvals

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on e	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
1980	ORIG-1	Approval	Type 5 - New Formulation or New Manufacturer	STANDARD	

ng 1 to 1 of 1 entries

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on e	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packa
2017	SUPPL-63	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2016	SUPPL-62	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2013	SUPPL-61	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_**
2008	SUPPL-60	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2007	SUPPL-58	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2007	SUPPL-57	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/**
2006	SUPPL-55	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2006	SUPPL-56	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2004	SUPPL-51	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2004	SUPPL-50	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/**
2003	SUPPL-49	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/**

on e	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packa
2002	SUPPL-54	Manufacturing (CMC)	
2001	SUPPL-53	Manufacturing (CMC)-Packaging	
2000	SUPPL-52	Manufacturing (CMC)	
1995	SUPPL-47	Manufacturing (CMC)-Formulation	
1994	SUPPL-48	Manufacturing (CMC)	
1993	SUPPL-46	Labeling	
1992	SUPPL-45	Manufacturing (CMC)	
1992	SUPPL-43	Manufacturing (CMC)-Packaging	

on e	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packa
1990	SUPPL-42	Manufacturing (CMC)-Control	
1987	SUPPL-36	Efficacy-New Indication	
1987	SUPPL-35	Efficacy-New Dosing Regimen	
1987	SUPPL-34	Labeling	
1987	SUPPL-26	Manufacturing (CMC)-Formulation	
1987	SUPPL-15	Labeling	
1986	SUPPL-20	Manufacturing (CMC)-Control	
1986	SUPPL-33	Manufacturing (CMC)-Packaging	

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