ıgs@FDA: FDA Approved ıg Products

ndex.cfm) | Previous Page

rug Application (NDA): 021920
ıny: BIONPHARMA INC

er Important Information from FDA
p://www.fda.gov/Drugs/DrugSafety/PostmarketDrug
tyInformationforPatientsandProviders/ucm110423.ht

ucts on NDA 021920

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ug me	Active Ingredients	Strength	Dosage Form/Route	Marketin Status
ROXEN UM	NAPROXEN SODIUM	EQ 200MG BASE	CAPSULE;ORAL	Over-the-counter

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oval Date(s) and History, Letters, Labels, Reviews for NDA 20

nal Approvals or Tentative Approvals

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tion te	Submission	Action Type	Submission Classification	Review Priority; Orphan Status
7/2006	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD

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tion te	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labe

tion te	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labe
5/2017	SUPPL-19	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata. Letter (PDF) (https://www.accessdata.**
1/2013	SUPPL-18	Labeling-Package Insert	**Label (PDF) (https://www.accessdata. Letter (PDF) (https://www.accessdata.**
3/2012	SUPPL-17	Labeling-Container/Carton Labels	**Letter (PDF) (https://www.accessdata.**
2/2010	SUPPL-13	Labeling-Container/Carton Labels	**Letter (PDF) (https://www.accessdata.**
4/2009	SUPPL-11	Labeling	**Label (PDF) (https://www.accessdata. Letter (PDF) (https://www.accessdata.**
5/2009	SUPPL-10	Labeling	**Letter (PDF) (https://www.accessdata.**

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OTC Drugs with the Same Active Ingredient, Strength and ge Form/Route