

# Drugs@FDA: FDA Approved Drug Products

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**Drug Application (NDA):** 021920  
**Company:** BIONPHARMA INC

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**For Important Information from FDA**  
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm110423.htm>

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**Products on NDA 021920** ▼

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status
NAPROXEN SODIUM	NAPROXEN SODIUM	EQ 200MG BASE	CAPSULE;ORAL	Over-the-counter

Showing 1 to 1 of 1 entries

**Approval Date(s) and History, Letters, Labels, Reviews for NDA 021920** ▲

**Final Approvals or Tentative Approvals**

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

Showing 1 to 1 of 1 entries

**Supplements**

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Submission Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels
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Submission Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels
6/2017	SUPPL-19	Labeling-Container/Carton Labels	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/suppl/041821Orig1s01.pdf</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/suppl/041821Orig1s01.pdf</a> )
1/2013	SUPPL-18	Labeling-Package Insert	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/suppl/041821Orig1s01.pdf</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/suppl/041821Orig1s01.pdf</a> )
3/2012	SUPPL-17	Labeling-Container/Carton Labels	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/suppl/041821Orig1s01.pdf</a> )
2/2010	SUPPL-13	Labeling-Container/Carton Labels	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/suppl/041821Orig1s01.pdf</a> )
4/2009	SUPPL-11	Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/suppl/041821Orig1s01.pdf</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/suppl/041821Orig1s01.pdf</a> )
5/2009	SUPPL-10	Labeling	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/suppl/041821Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/suppl/041821Orig1s01.pdf</a> )

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**Search for NDA 021920** 

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