Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 020067
Company: ATNAHS PHARMA US

- Medication Guide (http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017581s113,018164s063,020067s020lbl.pdf#page=22)

Products on NDA 020067

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
EC-NAPROSYN	NAPROXEN	375MG	TABLET, DELAYED RELEASE;ORAL	Prescription	AB	Yes	Yes
EC-NAPROSYN	NAPROXEN	500MG	TABLET, DELAYED RELEASE;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020067

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	Notes
10/14/1994	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD		Label is 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	Note

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	Note
03/10/2017	SUPPL-20	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2017/017581s113,018164s063,020067s020lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2017/017581Orig1s113,018164Orig1s063,020067Orig1s020ltr.pdf)**	
05/09/2016	SUPPL-19	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2016/017581s112,018164s062,020067s019lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2016/017581Orig1s112,018164Orig1s062,020067Orig1s019ltr.pdf)**	
03/22/2013	SUPPL-18	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2013/017581s111,018164s061,018965s020,020067s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2013/017581Orig1s111,018164Orig1s061,018965Orig1s020,020067Orig1s018ltr.pdf)**	
07/25/2008	SUPPL-17	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2008/017581s110,18164s60,18965s18,20067s17lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2008/017581s110,018164s060,018965s018,020067s017ltr.pdf)**	
09/20/2007	SUPPL-14	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2007/017581s108,18164s58,18965s16,20067s14lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2007/017581s108,18164s58,18965s16,20067s14ltr.pdf)**	
04/19/2007	SUPPL-13	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2007/017581s107, 018164s057, 018965s015, 020067s013_ltr.pdf)**	Label is not available on this site.
03/10/2006	SUPPL-10	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2006/020067s010,018965s013,018164s055, 017581s105lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/020067s010ltr.pdf)**	
01/24/2006	SUPPL-11	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label /2006/017581s106,018164s056,018965s014,020067s011lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter /2006/017581s106_020067s011_018164s056ltr.pdf)**	

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	Note
11/10/2004	SUPPL-6	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6ltr.pdf)**	
11/10/2004	SUPPL-4	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6ltr.pdf)**	
05/19/2003	SUPPL-5	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/20067slr005ltr.pdf)**	Label is not available on this site.
02/22/2002	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
11/09/2001	SUPPL-8	Manufacturing (CMC)-Packaging		Label is not available on this site.
07/09/1997	SUPPL-3	Manufacturing (CMC)		Label is not available on this site.
06/28/1996	SUPPL-2	Manufacturing (CMC)		Label is not available on this site.
12/06/1994	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.

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Labels for NDA 020067

Therapeutic Equivalents for NDA 020067