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

[EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VA.RAPPLNO=020067\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=Overview.Process%26VA.RAPPLNO=020067)

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

**Products on NDA 020067**

**CSVExcelPrint**

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**

**CSVExcelPrint**

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

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	Note
11/10/2004	SUPPL-6	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6ltr.pdf</a> )	
11/10/2004	SUPPL-4	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/17581s99,100,18164s50,51,18965s9,10,20067s4,6ltr.pdf</a> )	
05/19/2003	SUPPL-5	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/20067sir005ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/20067sir005ltr.pdf</a> )	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](#) ▼