

Drugs@FDA: FDA Approved Drug Products

(<https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=017581>)

(<https://twitter.com/intent/tweet?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=017581>)

(<https://www.linkedin.com/sharearticle?l=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=017581&title=Drugs@FDA: FDA Approved Drug Products&source=fda>)

(<https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=017581&description=Drugs@FDA: FDA Approved Drug Products>)

(<mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=017581>)

[index.cfm](#) | [Previous Page](#)

Drug Application (NDA): 017581
Company: ATNAHS PHARMA US

(<mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process%26varapplno=017581>)

[Information Guide](#)

http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017581s113,0181,0182,0183,020067s020lbl.pdf#page=22

[Details on NDA 017581](#)

8

Excel Print

g ne	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
OSYN	NAPROXEN	250MG	TABLET;ORAL	Prescription	AB
OSYN	NAPROXEN	375MG	TABLET;ORAL	Prescription	AB
OSYN	NAPROXEN	500MG	TABLET;ORAL	Prescription	AB

ng 1 to 3 of 3 entries

val Date(s) and History, Letters, Labels, Reviews for NDA 017581 ^

al Approvals or Tentative Approvals

Excel Print

on e	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
1976	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	

ng 1 to 1 of 1 entries

ements

Excel Print

on e	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packa

Year	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packa
2017	SUPPL-113	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2016	SUPPL-112	Labeling- Package Insert, Labeling- Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2013	SUPPL-111	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_)
2008	SUPPL-110	Labeling	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2007	SUPPL-108	Labeling	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2007	SUPPL-107	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/)
2006	SUPPL-105	Labeling	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2006	SUPPL-106	Labeling	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2004	SUPPL-100	Labeling	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2004	SUPPL-99	Labeling	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/)
2003	SUPPL-98	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/)
2002	SUPPL-103	Manufacturing (CMC)	

Application	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packaging
2001	SUPPL-102	Manufacturing (CMC)-Packaging	
2000	SUPPL-101	Manufacturing (CMC)	
1994	SUPPL-97	Manufacturing (CMC)	
1994	SUPPL-95	Manufacturing (CMC)-Control	
1994	SUPPL-87	Manufacturing (CMC)-Packaging	
1994	SUPPL-96	Manufacturing (CMC)-Packaging	
1992	SUPPL-93	Manufacturing (CMC)	
1992	SUPPL-89	Manufacturing (CMC)-Packaging	

Application	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packa
1991	SUPPL-86	Manufacturing (CMC)-Control	
1991	SUPPL-88	Manufacturing (CMC)-Packaging	
1989	SUPPL-80	Manufacturing (CMC)-Formulation	
1988	SUPPL-51	Manufacturing (CMC)	
1987	SUPPL-73	Efficacy-New Indication	
1987	SUPPL-65	Efficacy-New Dosing Regimen	
1986	SUPPL-72	Labeling	
1986	SUPPL-63	Manufacturing (CMC)-Formulation	

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.