Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020065
Company: BAUSCH AND LOMB

EMAIL (MAILTO:?SUBJECT_DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020065)

Products on NDA 020065

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Drug Name	Active ngredients	Strength	Dosage Form/Route	Marketing Status	TE Code
OPCON-A	NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	0.02675%;0.315%	SOLUTION/DROPS;OPHTHALMIC	Over-the-counter	None

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 020065

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
06/08/1994	ORIG-1	Approval	Type 5 - New Formulation or New Manufacturer	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
03/14/2016	SUPPL-22	Manufacturing (CMC)	
09/18/2015	SUPPL-21	Manufacturing (CMC)	
05/12/2015	SUPPL-20	Manufacturing (CMC)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
07/31/2007	SUPPL-17	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2**
04/20/2005	SUPPL 10	Manufacturing (CMC) Control	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2**
12/18/1996	SUPPL-15	Manufacturing (CMC)	
07/23/1996	SUPPL 14	Labeling	
07/23/1996	SUPPL-13	Labeling	
05/09/1996	SUPPL 11	Labeling	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
04/11/1996	SUPPL-8	Manufacturing (CMC)	
03/13/1996	SUPPL-9	Manufacturing (CMC)	
05/11/1995	SUPPL-5	Manufacturing (CMC)-Packaging	
11/29/1994	SUPPL-3	Manufacturing (CMC)-Control	
11/29/1994	SUPPL-2	Manufacturing (CMC)-Control	
10/11/1994	SUPPL-1	Manufacturing (CMC)-Control	

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Labels for NDA 020065

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