Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 019670
Company: BAYER HEALTHCARE LLC

Products on NDA 019670

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Co
CLARITIN-D	LORATADINE; PSEUDOEPHEDRINE SULFATE	5MG;120MG	TABLET, EXTENDED RELEASE;ORAL	Over-the-counter	Non

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 019670

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Pa Package I
11/14/1994	ORIG-1	Approval	Type 4 - New Combination	STANDARD	

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packag
11/25/2015	SUPPL-32	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov Letter (PDF) (https://www.accessdata.fda.go**
10/18/2013	SUPPL-31	Manufacturing (CMC)	
03/13/2013	SUPPL-30	Manufacturing (CMC)	
01/25/2010	SUPPL-22	Labeling-Container/Carton Labels	**Letter (PDF) (https://www.accessdata.fda.go**
04/23/2009	SUPPL-20	Labeling-Container/Carton Labels, Labeling-Package Insert	**Letter (PDF) (https://www.accessdata.fda.go Review (PDF) (https://www.accessdata.fda.g**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packag
07/30/2004	SUPPL-19	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov** **Letter (PDF) (https://www.accessdata.fda.go**
11/27/2002	SUPPL-18	Efficacy-Rx To OTC Switch	**Letter (PDF) (https://www.accessdata.fda.go** **Review (https://www.accessdata.fda.gov/dru**
03/04/2002	SUPPL-17	Manufacturing (CMC)-Expiration Date	**Review (https://www.accessdata.fda.gov/dru**
11/01/2000	SUPPL-15	Manufacturing (CMC)-Control	**Review (https://www.accessdata.fda.gov/dru**
09/13/2000	SUPPL-13	Manufacturing (CMC)-Control	**Review (https://www.accessdata.fda.gov/dru**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Packag
03/22/2000	SUPPL-14	Manufacturing (CMC)-Control	**Review (https://www.accessdata.fda.gov/dru**
01/27/1999	SUPPL-9	Manufacturing (CMC)-Control	**Review (https://www.accessdata.fda.gov/dru**
10/29/1998	SUPPL-12	Manufacturing (CMC)	**Review (https://www.accessdata.fda.gov/drugsatfda**
05/04/1998	SUPPL-7	Manufacturing (CMC)-Control	
04/29/1998	SUPPL-10	Labeling	

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