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New Drug Application (NDA): 019670

Company: BAYER HEALTHCARE LLC

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[Products on NDA 019670](#)



Exhibit 1109
IPR2017-00807
ARGENTUM

000001

CSV	Excel	Print					
Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
CLARITIN-D	LORATADINE; PSEUDOEPHEDRINE SULFATE	5MG;120MG	TABLET, EXTENDED RELEASE;ORAL	Over-the-counter	None	Yes	Yes

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 019670**Original Approvals or Tentative Approvals**

CSV	Excel	Print				
Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
11/14/1994	ORIG-1	Approval	Type 4 - New Combination	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements

CSV Excel Print			
Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
11/25/2015	SUPPL-32	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applet)
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.gov/drugsatfda_docs/applet)
04/23/2009	SUPPL-20	Labeling-Container/Carton Labels, Labeling-Package Insert	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applet) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/1)

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

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
03/22/2000	SUPPL-14	Manufacturing (CMC)-Control	Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/)
01/27/1999	SUPPL-9	Manufacturing (CMC)-Control	Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/1999/)
10/29/1998	SUPPL-12	Manufacturing (CMC)	Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/1998/019670)
05/04/1998	SUPPL-7	Manufacturing (CMC)-Control	
04/29/1998	SUPPL-10	Labeling	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
01/23/1998	SUPPL-8	Manufacturing (CMC)	Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/1998/DTOC.cfml)
07/21/1997	SUPPL-5	Manufacturing (CMC)-Control	
07/14/1997	SUPPL-6	Labeling	
02/07/1997	SUPPL-1	Manufacturing (CMC)-Control	
02/05/1997	SUPPL-4	Labeling	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
04/29/1996	SUPPL-3	Labeling	
09/22/1995	SUPPL-2	Manufacturing (CMC)-Control	

Showing 1 to 22 of 22 entries

Labels for NDA 019670



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

