Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020121
Company: GLAXOSMITHKLINE

Products on NDA 020121

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
FLONASE	**FLUTICASONE PROPIONATE**	**0.05MG/SPRAY **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons****	**SPRAY, METERED;NASAL**	**Discontinued**	**None**	**Yes**	**No**

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 020121

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
10/19/1994	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD		Label is not available on this site.

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
01/07/2019	SUPPL-45	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020121s045lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/020121Orig1s045ltr.pdf)**
01/23/2015	SUPPL-44	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020121s044lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/020121Orig1s044ltr.pdf)**
06/17/2014	SUPPL-43	Manufacturing (CMC)	
06/17/2014	SUPPL-42	Manufacturing (CMC)	
06/19/2013	SUPPL-41	Manufacturing (CMC)	
03/26/2004	SUPPL-30	Labeling	**Label (PDF)** **(https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/20549slr016,20548slr020,20121slr030_flona** **Letter (PDF)** **(https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/20549slr016,20548slr020,20121slr030lt**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
05/01/2003	SUPPL-28	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/020121s028lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/20121se8-028ltr.pdf)**
05/23/2002	SUPPL-23	Efficacy-New Dosing Regimen	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20121s023ltr.pdf)**
05/09/2002	SUPPL-20	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/NDA20121S011.pdf)**
05/09/2002	SUPPL-13	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/NDA20121S011.pdf)**
05/09/2002	SUPPL-11	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/NDA20121S011.pdf)**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
05/07/2002	SUPPL-26	Manufacturing (CMC)-Packaging	
03/04/2002	SUPPL-25	Manufacturing (CMC)-Control	
02/19/2002	SUPPL-24	Manufacturing (CMC)-Control	
08/03/2001	SUPPL-17	Manufacturing (CMC)-Control	
07/09/2001	SUPPL-22	Manufacturing (CMC)-Control	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
06/25/2001	SUPPL-21	Manufacturing (CMC)-Control	
09/26/2000	SUPPL-8	Manufacturing (CMC)-Control	
06/20/2000	SUPPL-16	Manufacturing (CMC)	
05/17/2000	SUPPL-15	Manufacturing (CMC)-Control	
02/18/2000	SUPPL-12	Manufacturing (CMC)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
12/11/1998	SUPPL-9	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20121-S009_FLONASE_prntlbl.pd** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20121s9ltr.pdf)** **Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20121S009_Flonase.cfm)**
10/01/1998	SUPPL-10	Labeling	
02/18/1998	SUPPL-6	Manufacturing (CMC)-Control	
10/31/1997	SUPPL-5	Efficacy-New Indication	**Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20121.pdf)**
12/12/1996	SUPPL-4	Labeling	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
03/27/1996	SUPPL-3	Labeling	
08/01/1995	SUPPL-2	Manufacturing (CMC)-Control	

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Labels for NDA 020121