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New Drug Application (NDA): 020121
Company: GLAXOSMITHKLINE

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status
FLONASE	FLUTICASONE PROPIONATE	0.05MG/SPRAY **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	SPRAY, METERED;NASAL	Discontinued

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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
10/19/1994	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	

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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/2019/01072019_spl/spl_r1.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2019/01072019_spl/spl_r1.pdf)
01/23/2015	SUPPL-44	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/01232015_spl/spl_r1.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2015/01232015_spl/spl_r1.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/2004/20549s1r0.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2004/20549s1r0.pdf)

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/2003/008491s010.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/008491s010.pdf)
05/23/2002	SUPPL-23	Efficacy-New Dosing Regimen	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008491s010.pdf)
05/09/2002	SUPPL-20	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008491s010.pdf)
05/09/2002	SUPPL-13	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008491s010.pdf)
05/09/2002	SUPPL-11	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008491s010.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	

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