# Drugs@FDA: FDA-Approved Drugs

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EVENT=OVERVIEW.PROCESS&APPLNO=020121)

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**New Drug Application (NDA):** 020121
**Company:** GLAXOSMITHKLINE

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX
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## Products on NDA 020121

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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| FLONASE | FLUTICASONE PROPIONATE | 0.05MG/SPRAY **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** | SPRAY, METERED;NASAL | Discontinued | |

Showing 1 to 1 of 1 entries

## 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/20**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |
| 01/23/2015 | SUPPL-44 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/20**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |
| 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/2004/20549slr0**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/2054** |

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| 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/20**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |
| 05/23/2002 | SUPPL-23 | Efficacy-New Dosing Regimen | **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |
| 05/09/2002 | SUPPL-20 | Labeling | **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |
| 05/09/2002 | SUPPL-13 | Labeling | **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |
| 05/09/2002 | SUPPL-11 | Labeling | **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett** |

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| 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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