


# Drugs@FDA: FDA-Approved Drugs


 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=020121\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=020121)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA-APPROVED DRUGS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=020121\)](https://twitter.com/intent/tweet/?text=Drugs@FDA: FDA-Approved Drugs&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=020121)

 [LINKEDIN \(HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=020121&TITLE=DRUGS@FDA: FDA-APPROVED DRUGS&SOURCE=FDA\)](https://www.linkedin.com/sharearticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=020121&title=Drugs@FDA: FDA-Approved Drugs&source=fda)

 [PIN IT \(HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=020121&DESCRIPTION=DRUGS@FDA: FDA-APPROVED DRUGS\)](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=020121&description=Drugs@FDA: FDA-Approved Drugs)




 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA-APPROVED DRUGS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=020121\)](mailto:?subject=Drugs@FDA: FDA-Approved Drugs&body=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=020121)

 PRINT

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 020121  
Company: GLAXOSMITHKLINE

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020121\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process%26varapplno=020121)

**Products on NDA 020121**

[CSV](#)
[Excel](#)
[Print](#)

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FLONASE	FLUTICASONE PROPIONATE	0.05MG/SPRAY **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	SPRAY, METERED;NASAL	Discontinued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

[CSV](#)
[Excel](#)
[Print](#)

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	

Showing 1 to 1 of 1 entries

**Supplements**

[CSV](#)
[Excel](#)
[Print](#)

<b>Action Date</b>	<b>Submission</b>	<b>Supplement Categories or Approval Type</b>	<b>Letters, Reviews, Labels, Patient Package Insert</b>
01/07/2019	SUPPL-45	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/01072019_spl/spl_r1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/01072019_spl/spl_r1.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appl/2019/01072019_spl/spl_r1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appl/2019/01072019_spl/spl_r1.pdf</a> )
01/23/2015	SUPPL-44	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/01232015_spl/spl_r1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/01232015_spl/spl_r1.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appl/2015/01232015_spl/spl_r1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appl/2015/01232015_spl/spl_r1.pdf</a> )
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) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/20549s1r0.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/20549s1r0.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appl/2004/20549s1r0.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appl/2004/20549s1r0.pdf</a> )

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) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/008121s010.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/008121s010.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/008121s010.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/008121s010.pdf</a> )
05/23/2002	SUPPL-23	Efficacy-New Dosing Regimen	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s023.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s023.pdf</a> )
05/09/2002	SUPPL-20	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s020.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s020.pdf</a> )
05/09/2002	SUPPL-13	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s013.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s013.pdf</a> )
05/09/2002	SUPPL-11	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s011.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/008121s011.pdf</a> )

<b>Action Date</b>	<b>Submission</b>	<b>Supplement Categories or Approval Type</b>	<b>Letters, Reviews, Labels, Patient Package Insert</b>
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	

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.