

# Drugs@FDA: FDA Approved Drug Products

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**New Drug Application (NDA):** 022051

**Company:** GLAXOSMITHKLINE CONS

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**Products on NDA 022051**

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| Drug Name                        | Active Ingredients  | Strength       | Dosage Form/Route    | Marketing Status | TE Code | RLD | RS  |
|----------------------------------|---------------------|----------------|----------------------|------------------|---------|-----|-----|
| FLONASE SENSIMIST ALLERGY RELIEF | FLUTICASONE FUROATE | 0.0275MG/SPRAY | SPRAY, METERED;NASAL | Over-the-counter | None    | Yes | Yes |

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**Approval Date(s) and History, Letters, Labels, Reviews for NDA 022051****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                                                                         |
|-------------|------------|-------------|--------------------------------|--------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 04/27/2007  | ORIG-1     | Approval    | Type 2 - New Active Ingredient | STANDARD                       | <b>Review (<a href="https://www.accessdata.fda.gov/drugsatfda_doc">https://www.accessdata.fda.gov/drugsatfda_doc</a></b> |

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## Supplements

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| Action Date | Submission | Supplement Categories or Approval Type      | Letters, Reviews, Labels, Patient Package Insert                                                                                                                                                                                                                                                                                                                                                                       | Note                                 |
|-------------|------------|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| 08/23/2017  | SUPPL-17   | Labeling-Container/Carton Labels            | <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/022051Orig1s017ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/022051Orig1s017ltr.pdf</a> )<br><b>Review (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/review/2018/022051Orig1s017.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/review/2018/022051Orig1s017.pdf</a> ) | Label is not available on this site. |
| 04/05/2017  | SUPPL-14   | Labeling-Container/Carton Labels            | <b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022051Orig1s014lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022051Orig1s014lbl.pdf</a> )<br><b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022051Orig1s014ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022051Orig1s014ltr.pdf</a> )       |                                      |
| 08/02/2016  | SUPPL-13   | Efficacy-Rx To OTC Switch                   | <b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022051Orig1s013lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022051Orig1s013lbl.pdf</a> )                                                                                                                                                                                                                 |                                      |
| 05/21/2015  | SUPPL-11   | Labeling-Package Insert                     |                                                                                                                                                                                                                                                                                                                                                                                                                        | Label is not available on this site. |
| 08/21/2012  | SUPPL-8    | Efficacy-Labeling Change With Clinical Data |                                                                                                                                                                                                                                                                                                                                                                                                                        | Label is not available on this site. |
| 10/13/2011  | SUPPL-7    | Labeling-Package Insert                     |                                                                                                                                                                                                                                                                                                                                                                                                                        | Label is not available on this site. |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note                                 |
|-------------|------------|----------------------------------------|--------------------------------------------------|--------------------------------------|
| 09/01/2011  | SUPPL-5    | Labeling-Package Insert                |                                                  | Label is not available on this site. |
| 07/28/2009  | SUPPL-2    | Labeling                               |                                                  | Label is not available on this site. |

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**Labels for NDA 022051**



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

