Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 204275
Company: GLAXO GRP LTD

Products on NDA 204275

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
BREO ELLIPTA	FLUTICASONE FUROATE; VILANTEROL TRIFENATATE	0.1MG/INH;EQ 0.025MG BASE/INH	POWDER;INHALATION	Prescription	None	Yes	Yes
BREO ELLIPTA	FLUTICASONE FUROATE; VILANTEROL TRIFENATATE	0.2MG/INH;EQ 0.025MG BASE/INH	POWDER;INHALATION	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 204275

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Pati
05/10/2013	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	**Label (PDF) (https://www.accessda Letter (PDF) (https://www.accessda Review (https://www.accessdata.fd**

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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-17	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/**
12/20/2017	SUPPL-15	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/**
05/15/2017	SUPPL-12	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/**
10/31/2016	SUPPL-11	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/**
02/16/2016	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
10/21/2015	SUPPL-8	Manufacturing (CMC)	
09/15/2015	SUPPL-4	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/**
08/11/2015	SUPPL-5	Manufacturing (CMC)	
04/30/2015	SUPPL-1	Efficacy-New Dosing Regimen	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/**
03/02/2015	SUPPL-2	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/**

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Labels for NDA 204275