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New Drug Application (NDA): 204275

Company: GLAXO GRP LTD

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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, Patient Package Insert
05/10/2013	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020474orig1s1.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/020474orig1s1.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/020474orig1s1.pdf)

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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/2019/204747suppl17.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/204747suppl17.pdf)
12/20/2017	SUPPL-15	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204747suppl15.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/204747suppl15.pdf)
05/15/2017	SUPPL-12	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204747suppl12.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/204747suppl12.pdf)
10/31/2016	SUPPL-11	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204747suppl11.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204747suppl11.pdf)
02/16/2016	SUPPL-9	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204747suppl9.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204747suppl9.pdf)

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/2015/204275Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/204275Orig1s001.pdf)
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/2015/204275Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/204275Orig1s001.pdf)
03/02/2015	SUPPL-2	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204275Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/204275Orig1s001.pdf)

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Labels for NDA 204275