

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations												
Mkt.Status	Active Ingredient	Proprietary Name	Appl No	Product Number	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder	Approval Date
RX	AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE	DYMISTA	N202236	001	SPRAY, METERED	NASAL	EQ 0.125MG BASE/SPRAY; 0.05MG/SPRAY	AB	RLD	RS	MYLAN SPECIALTY LP	May 1, 2012
RX	AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE	AZELASTINE HYDROCHLORIDE AND FLUTICASONE PROPIONATE	A207712	001	SPRAY, METERED	NASAL	EQ 0.125MG BASE/SPRAY; 0.05MG/SPRAY	AB			APOTEX INC	Apr 28, 2017
DISCN	FLUTICASONE PROPIONATE	FLONASE	N020121	001	SPRAY, METERED	NASAL	0.05MG/SPRAY **Federal Register determination that pr				GLAXOSMITHKLINE	Oct 19, 1994
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076504	001	SPRAY, METERED	NASAL	0.05MG/SPRAY	AB		RS	WEST-WARD PHARMACEUTICALS INTERN	Feb 22, 2006
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A077538	001	SPRAY, METERED	NASAL	0.05MG/SPRAY	AB			APOTEX INC RICHMOND HILL	Sep 12, 2007
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A077570	001	SPRAY, METERED	NASAL	0.05MG/SPRAY	AB			HI TECH PHARMACAL CO INC	Jan 16, 2008
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A078492	001	SPRAY, METERED	NASAL	0.05MG/SPRAY	AB			WOCKHARDT EU OPERATIONS (SWISS) AC	Jan 9, 2012
OTC	FLUTICASONE PROPIONATE	FLONASE ALLERGY RELIEF	N205434	001	SPRAY, METERED	NASAL	0.05MG/SPRAY		RLD	RS	GLAXOSMITHKLINE CONSUMER HEALTHC	Jul 23, 2014
OTC	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A208150	001	SPRAY, METERED	NASAL	0.05MG/SPRAY				APOTEX INC	Feb 29, 2016
OTC	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A207957	001	SPRAY, METERED	NASAL	0.05MG/SPRAY				WEST-WARD PHARMACEUTICALS INTERN	May 26, 2016
RX	FLUTICASONE PROPIONATE	XHANCE	N209022	001	SPRAY, METERED	NASAL	0.093MG		RLD	RS	OPTNOSE US INC	Sep 18, 2017
DISCN	FLUTICASONE PROPIONATE	FLOVENT	N020549	001	POWDER	INHALATION	0.044MG/INH				GLAXOSMITHKLINE	Nov 7, 1997
DISCN	FLUTICASONE PROPIONATE	FLOVENT	N020549	002	POWDER	INHALATION	0.088MG/INH				GLAXOSMITHKLINE	Nov 7, 1997
DISCN	FLUTICASONE PROPIONATE	FLOVENT	N020549	003	POWDER	INHALATION	0.22MG/INH				GLAXOSMITHKLINE	Nov 7, 1997
RX	FLUTICASONE PROPIONATE	FLOVENT DISKUS 100	N020833	002	POWDER	INHALATION	0.1MG/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Sep 29, 2000
RX	FLUTICASONE PROPIONATE	FLOVENT DISKUS 250	N020833	003	POWDER	INHALATION	0.25MG/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Sep 29, 2000
RX	FLUTICASONE PROPIONATE	FLOVENT DISKUS 50	N020833	001	POWDER	INHALATION	0.05MG/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Sep 29, 2000
RX	FLUTICASONE PROPIONATE	ARMONAIR RESPICLICK	N208798	001	POWDER	INHALATION	0.055MG/INH		RLD		TEVA PHARMACEUTICAL INDUSTRIES LTD	Jan 27, 2017
RX	FLUTICASONE PROPIONATE	ARMONAIR RESPICLICK	N208798	002	POWDER	INHALATION	0.113MG/INH		RLD		TEVA PHARMACEUTICAL INDUSTRIES LTD	Jan 27, 2017
RX	FLUTICASONE PROPIONATE	ARMONAIR RESPICLICK	N208798	003	POWDER	INHALATION	0.232MG/INH		RLD	RS	TEVA PHARMACEUTICAL INDUSTRIES LTD	Jan 27, 2017
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	ADVAIR DISKUS 100/50	N021077	001	POWDER	INHALATION	0.1MG/INH; EQ 0.05MG BASE/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Aug 24, 2000
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	ADVAIR DISKUS 250/50	N021077	002	POWDER	INHALATION	0.25MG/INH; EQ 0.05MG BASE/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Aug 24, 2000
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	ADVAIR DISKUS 500/50	N021077	003	POWDER	INHALATION	0.5MG/INH; EQ 0.05MG BASE/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Aug 24, 2000
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	AIRDUO RESPICLICK	N208799	001	POWDER	INHALATION	0.055MG/INH; EQ 0.014MG BASE/INH		RLD		TEVA PHARMACEUTICAL INDUSTRIES LTD	Jan 27, 2017
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	AIRDUO RESPICLICK	N208799	002	POWDER	INHALATION	0.113MG/INH; EQ 0.014MG BASE/INH		RLD		TEVA PHARMACEUTICAL INDUSTRIES LTD	Jan 27, 2017
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	AIRDUO RESPICLICK	N208799	003	POWDER	INHALATION	0.232MG/INH; EQ 0.014MG BASE/INH		RLD	RS	TEVA PHARMACEUTICAL INDUSTRIES LTD	Jan 27, 2017
RX	FLUTICASONE PROPIONATE	CUTIVATE	N019957	001	OINTMENT	TOPICAL		0% AB	RLD	RS	FOUGERA PHARMACEUTICALS INC	Dec 14, 1990
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076300	001	OINTMENT	TOPICAL		0% AB			FOUGERA PHARMACEUTICALS INC	May 14, 2004
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076668	001	OINTMENT	TOPICAL		0% AB			PERRIGO NEW YORK INC	May 14, 2004
DISCN	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A077145	001	OINTMENT	TOPICAL		0%			TARO PHARMACEUTICAL INDUSTRIES LTD	Jun 14, 2005
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A077168	001	OINTMENT	TOPICAL		0% AB			G AND W LABORATORIES INC	Mar 3, 2006
RX	FLUTICASONE PROPIONATE	CUTIVATE	N021152	001	LOTION	TOPICAL		0% AB	RLD	RS	FOUGERA PHARMACEUTICALS INC	Mar 31, 2005
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A090759	001	LOTION	TOPICAL		0% AB			GLENMARK GENERICS LIMITED	May 2, 2011
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A091553	001	LOTION	TOPICAL		0% AB			PERRIGO ISRAEL PHARMACEUTICALS LTD	Jul 30, 2013
DISCN	FLUTICASONE PROPIONATE	CUTIVATE	N019958	001	CREAM	TOPICAL	0.05% **Federal Register determination that product wa		RLD		FOUGERA PHARMACEUTICALS INC	Dec 18, 1990
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076451	001	CREAM	TOPICAL		0% AB			FOUGERA PHARMACEUTICALS INC	May 14, 2004
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076793	001	CREAM	TOPICAL		0% AB		RS	PERRIGO NEW YORK INC	May 14, 2004
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076633	001	CREAM	TOPICAL		0% AB			TOLMAR INC	May 14, 2004
DISCN	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A076865	001	CREAM	TOPICAL		0%			NESHER PHARMACEUTICALS USA LLC	Sep 10, 2004
RX	FLUTICASONE PROPIONATE	FLUTICASONE PROPIONATE	A077055	001	CREAM	TOPICAL		0% AB			G AND W LABORATORIES INC	Jun 30, 2006
DISCN	FLUTICASONE PROPIONATE	FLOVENT	N020548	001	AEROSOL, METERED	INHALATION	0.044MG/INH				GLAXOSMITHKLINE	Mar 27, 1996
DISCN	FLUTICASONE PROPIONATE	FLOVENT	N020548	002	AEROSOL, METERED	INHALATION	0.11MG/INH				GLAXOSMITHKLINE	Mar 27, 1996
DISCN	FLUTICASONE PROPIONATE	FLOVENT	N020548	003	AEROSOL, METERED	INHALATION	0.22MG/INH				GLAXOSMITHKLINE	Mar 27, 1996
RX	FLUTICASONE PROPIONATE	FLOVENT HFA	N021433	003	AEROSOL, METERED	INHALATION	0.044MG/INH		RLD	RS	GLAXO GROUP LTD DBA GLAXOSMITHKLI	May 14, 2004
RX	FLUTICASONE PROPIONATE	FLOVENT HFA	N021433	002	AEROSOL, METERED	INHALATION	0.11MG/INH		RLD	RS	GLAXO GROUP LTD DBA GLAXOSMITHKLI	May 14, 2004
RX	FLUTICASONE PROPIONATE	FLOVENT HFA	N021433	001	AEROSOL, METERED	INHALATION	0.22MG/INH		RLD	RS	GLAXO GROUP LTD DBA GLAXOSMITHKLI	May 14, 2004
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	ADVAIR HFA	N021254	001	AEROSOL, METERED	INHALATION	0.045MG/INH; EQ 0.021MG BASE/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Jun 8, 2006
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	ADVAIR HFA	N021254	002	AEROSOL, METERED	INHALATION	0.115MG/INH; EQ 0.021MG BASE/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Jun 8, 2006
RX	FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	ADVAIR HFA	N021254	003	AEROSOL, METERED	INHALATION	0.23MG/INH; EQ 0.021MG BASE/INH		RLD	RS	GLAXO GROUP LTD ENGLAND DBA GLAXC	Jun 8, 2006

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