

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Prescription to Over-the-Counter (OTC) Switch List

## January 1 through March 31, 2016

There are no switches for this period of time.

## January 1 through December 31, 2015

NDA	Drug Name	Purpose	Approval Date
NDA 20476/S-032	Rhinocort Allergy Spray (budesonide)	Allergic rhinitis	AP 3-23-15

## January 1 through December 31, 2014

NDA	Drug Name	Purpose	Approval Date
NDA 204655	Nexium 24 HR (esomeprazole magnesium)	Frequent heartburn	AP 3-28-14
NDA 205434	Flonase Allergy Relief (fluticasone propionate)	Allergic rhinitis	AP 7-23-14

## January 1 through December 31, 2013

NDA	Drug Name	Purpose	Approval Date
NDA 202211	Oxytrol for Women	Overactive bladder	AP 1-25-13
NDA 020468/S-035	Nasacort Allergy 24HR (nasal spray)	Allergic rhinitis	AP 10-11-13

## January 1 through December 31, 2012

There are no switches for this period of time.

## January 1 through December 31, 2011

NDA	Drug Name	Purpose	Approval Date
NDA 20-786/S-027	Allegra D 12 hr	Antihistamine	AP 1-24-11
NDA 21-704/S-008	Allegra 24 hr	Antihistamine	AP 1-24-11
NDA 20872/S-023	Allegra	Antihistamine	AP 1-25-11
NDA 201-373			
NDA 21-909/S-003			

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106378.htm>



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**MEDA\_APTX03502994**

CIP2077  
Argentum Pharmaceuticals LLC v. Cipla Ltd.  
IPR2017-00807

**PTX0407-00001**

**January 1 through December 31, 2010**

There are no switches for this period of time.

**January 1 through December 31, 2009**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 22-327 <sup>2</sup>	Prevacid 24 HR	Acid reducer/PPI	AP 5-18-09
NDA 22-281 <sup>2</sup>	Zegerid OTC	Acid reducer/PPI	AP 12-1-09

**January 1 through December 31, 2008**

There are no switches for this period of time.

**January 1 through December 31, 2007**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 21-887 <sup>2</sup>	alli	Weight Loss Aid	AP 2-7-07
NDA 21-150/S-007	Zyrtec-D	Antihistamine and Nasal Decongestant	AP 11-9-07
NDA 22-155	Children's Zyrtec Allergy and Children's Zyrtec Hives Relief (syrup)	Antihistamine	AP 11-16-07
NDA 21-621/S-005	Children's Zyrtec Allergy and Children's Zyrtec Hives Relief (chewable tablets)	Antihistamine	AP 11-16-07
NDA 19-835/S-022	Zyrtec Allergy and Zyrtec Hives Relief (tablets)	Antihistamine	AP 11-16-07

**January 1 through December 31, 2006**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 21-958	Lamisil Derm Gel	Topical Antifungal	AP 7-24-06
NDA 21-045	Plan B	Emergency Contraceptive	AP 8-24-06
NDA 22-015	MiraLax	Laxative	AP 10-6-06
NDA 21-066	Zaditor	Antihistamine Eye Drop	AP 10-19-06
NDA 21-996	Alaway	Antihistamine Eye Drop	AP 12-1-06

**January 1 through December 31, 2005**

There are no switches for this period of time.

**January 1 through December 31, 2004**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 21-620 <sup>1</sup>	Mucinex DM ER Tablet	Expectorant/Cough Suppressant	AP 4-29-04
NDA 21-585 <sup>1</sup>	Mucinex D ER Tablet	Expectorant/Decongestant	AP 6-22-04

**January 1 through December 31, 2003**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 21-229 <sup>2</sup>	Prilosec OTC	Acid reducer/PPI	AP 6-20-03
NDA 19-658/S-020 NDA 20-704/S-009 NDA 20-641/S-011	Claritin Hives Relief Tablets, Reditabs and Syrup	Antihistamine	AP 11-19-03

**January 1 through December 31, 2002**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 20-150	Nicotrol TD	Smoking Cessation	AP 3-21-02
NDA 21-282 <sup>1</sup>	Mucinex ER Tablet	Expectorant	AP 7-12-02
NDA 19-658/S-018 NDA 20-704/S-008 NDA 20-641/S-009	Claritin Tablets, Reditabs and Syrup	Antihistamine	AP 11-27-02
NDA 19-670/S-018	Claritin-D	Antihistamine/Decongestant	AP 11-27-02
NDA 20-470/S-016	Claritin-D 24-hour	Antihistamine/ Decongestant	AP 11-27-02

**January 1 through December 31, 2001**

<b>NDA</b>	<b>Drug Name</b>	<b>Purpose</b>	<b>Approval Date</b>
NDA 21-261	Monistat 3 combo pk	Vaginal Antifungal	AP 2-2-01
NDA 21-308	Monistat 1 (supp)	Vaginal Antifungal	AP 6-29-01
NDA 21-307	Lotrimin Ultra	Topical Antifungal	AP 12-7-01

<sup>1</sup>These NDAs are not **true** switches since these products were marketed as prescription products without an approved NDA prior to being approved for OTC marketing under an NDA.

<sup>2</sup>These NDAs are not **true** switches since the conditions of use were not marketed as a prescription product under an approved NDA prior to being approved for marketing OTC.

#### Resources for You

- [Over-the-Counter \(OTC\) Related Federal Register Notices, Ingredient References, and other Regulatory Information \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106368.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106368.htm)

More in [About the Center for Drug Evaluation and Research \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm)

[CDER Offices and Divisions \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm)

[Drug Safety Oversight Board \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082129.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082129.htm)

[Jobs at the Center for Drug Evaluation and Research \(CDER\) \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm081244.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm081244.htm)

[Meeting Presentations \(Drugs\) \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm)

[CDER Exclusivity Board \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm323412.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm323412.htm)

[FAQs about CDER \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/FAQsaboutCDER/default.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/FAQsaboutCDER/default.htm)

[Reports & Budgets \(CDER\) \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/default.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/default.htm)



[Manual of Policies & Procedures \(CDER\) \(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm\)](/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm)

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