

# Drugs@FDA: FDA-Approved Drugs

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 021071  
Company: WOODWARD

[EMAIL \(MAILTO: ?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021071\)](mailto:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021071)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/021071s052lbl.pdf#page=38\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021071s052lbl.pdf#page=38)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm143349.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm143349.htm)

## Products on NDA 021071

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
AVANDIA	ROSIGLITAZONE MALEATE	EQ 2MG BASE	TABLET;ORAL	Discontinued	None	Yes	No
AVANDIA	ROSIGLITAZONE MALEATE	EQ 4MG BASE	TABLET;ORAL	Discontinued	None	Yes	No
AVANDIA	ROSIGLITAZONE MALEATE	EQ 8MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No

Showing 1 to 3 of 3 entries

## Approval Date(s) and History, Letters, Labels, Reviews for NDA 021071

### Original Approvals or Tentative Approvals

CSV Excel Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
05/25/1999	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/21071lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/21071lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/1999/21071ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/1999/21071ltr.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/21071_Avandia.cfm">Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/21071_Avandia.cfm)</a>	

Showing 1 to 1 of 1 entries

### Supplements

CSV Excel Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/05/2019	SUPPL-52	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021071s052lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021071s052lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/021071Orig1s052ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/021071Orig1s052ltr.pdf)</a>	
09/19/2016	SUPPL-51	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021071s051lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021071s051lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/021071Orig1s051ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/021071Orig1s051ltr.pdf)</a>	
12/16/2015	SUPPL-50	REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/021071Orig1s050,0214100Orig1s039,0217000Orig1s022ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/021071Orig1s050,0214100Orig1s039,0217000Orig1s022ltr.pdf)</a>	Label is not available on this site.
05/07/2014	SUPPL-49	REMS-Assessment, REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021071Orig1s047,s048,s049ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021071Orig1s047,s048,s049ltr.pdf)</a>	

Novo Nordisk Exhibit 2486

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
05/07/2014	SUPPL-48	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021071Orig1s047_s048_s049ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021071Orig1s047_s048_s049ltr.pdf</a> ) Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/021071Orig1s048.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/021071Orig1s048.pdf</a> )	
05/07/2014	SUPPL-47	REMS-Modified	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021071Orig1s047_s048_s049ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021071Orig1s047_s048_s049ltr.pdf</a> )	
09/16/2013	SUPPL-45	REMS-Assessment, REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/021071Orig1s045_021410Orig1s034_021700Orig1s016ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/021071Orig1s045_021410Orig1s034_021700Orig1s016ltr.pdf</a> )	Label is not available on this site.
01/25/2013	SUPPL-44	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/021071Orig1s044_021410Orig1s032_021700Orig1s015ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/021071Orig1s044_021410Orig1s032_021700Orig1s015ltr.pdf</a> )	Label is not available on this site.
05/30/2012	SUPPL-41	REMS-Modified	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021071s041lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021071s041lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/021071s041_021410s030_021700s013ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/021071s041_021410s030_021700s013ltr.pdf</a> )	
11/13/2011	SUPPL-40	REMS-Modified	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s040lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s040lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021071s040_021410s029_021700s012ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021071s040_021410s029_021700s012ltr.pdf</a> )	
05/18/2011	SUPPL-39	REMS-Proposal	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s039lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s039lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021071s039_021410s027_021700s011ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021071s039_021410s027_021700s011ltr.pdf</a> )	
02/03/2011	SUPPL-38	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s038_021410s026_021700s010lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s038_021410s026_021700s010lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021071s038_021410s026_021700s010ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021071s038_021410s026_021700s010ltr.pdf</a> )	
10/20/2008	SUPPL-34	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s034lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s034lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s034ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s034ltr.pdf</a> )	
07/10/2008	SUPPL-26	Efficacy-Labeling Change With Clinical Data	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s026lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s026lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s026ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s026ltr.pdf</a> )	
02/22/2008	SUPPL-32	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s032lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s032lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s032ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s032ltr.pdf</a> )	
01/16/2008	SUPPL-29	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s029lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s029lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s029ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021071s029ltr.pdf</a> )	
11/14/2007	SUPPL-31	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s031lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s031lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s031ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s031ltr.pdf</a> )	
09/20/2007	SUPPL-27	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s027lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s027lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s027ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s027ltr.pdf</a> )	
08/14/2007	SUPPL-28	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s028lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s028lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s028ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s028ltr.pdf</a> )	
06/25/2007	SUPPL-24	Labeling		Label is not available on this site.
04/23/2007	SUPPL-23	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s023lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s023lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s023ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021071s023ltr.pdf</a> )	
06/16/2006	SUPPL-21	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021071s019_021071s021LTR.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021071s019_021071s021LTR.pdf</a> )	
06/16/2006	SUPPL-19	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021071s019_021071s021LTR.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021071s019_021071s021LTR.pdf</a> )	
04/21/2006	SUPPL-16	Efficacy-Labeling Change With Clinical Data	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s016lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021071s016LTR.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021071s016LTR.pdf</a> )	
07/29/2005	SUPPL-15	Efficacy-New Patient Population	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s015lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021071s015ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021071s015ltr.pdf</a> )	
05/12/2005	SUPPL-10	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s010lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s010lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021071s010ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021071s010ltr.pdf</a> )	

Novo Nordisk Exhibit 2486

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/28/2005	SUPPL-12	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s012lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s012lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/21071s012ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/21071s012ltr.pdf</a> )	
01/04/2005	SUPPL-14	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s014lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s014lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/21071s014_21410s009ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/21071s014_21410s009ltr.pdf</a> ) Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021071_s014_Avandia Tabs.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021071_s014_Avandia Tabs.pdf</a> )	
05/19/2004	SUPPL-9	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/21071slr009_21410slr005_006ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/21071slr009_21410slr005_006ltr.pdf</a> )	Label is not available on this site.
02/27/2003	SUPPL-4	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/021071s004lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/021071s004lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/21071se1-004ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/21071se1-004ltr.pdf</a> ) Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/021071_S004_AVANDIA.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/021071_S004_AVANDIA.pdf</a> )	
12/03/2002	SUPPL-8	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21071slr008ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21071slr008ltr.pdf</a> )	Label is not available on this site.
02/08/2001	SUPPL-6	Labeling		Label is not available on this site.
12/13/2000	SUPPL-7	Manufacturing (CMC)-Control		Label is not available on this site.
12/05/2000	SUPPL-5	Labeling		Label is not available on this site.
07/11/2000	SUPPL-2	Labeling		Label is not available on this site.
07/03/2000	SUPPL-3	Manufacturing (CMC)		Label is not available on this site.
04/03/2000	SUPPL-1	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia_prntlbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia_prntlbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2000/21071S1LTR.PDF">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2000/21071S1LTR.PDF</a> ) Review ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia.cfm">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia.cfm</a> )	

Showing 1 to 37 of 37 entries

[Labels for NDA 021071](#)



# Drugs@FDA: FDA-Approved Drugs

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 021071

Company: WOODWARD

[EMAIL \(MAILTO: ?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021071\)](mailto:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021071)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/021071s052lbl.pdf#page=38\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021071s052lbl.pdf#page=38)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm143349.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm143349.htm)

**Products on NDA 021071** ▼

**Approval Date(s) and History, Letters, Labels, Reviews for NDA 021071** ▼

**Labels for NDA 021071** ▲

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/05/2019	SUPPL-52	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021071s052lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021071s052lbl.pdf)</a>	
09/19/2016	SUPPL-51	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021071s051lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021071s051lbl.pdf)</a>	
05/07/2014	SUPPL-49	REMS-Assessment	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf)</a>	
05/07/2014	SUPPL-49	REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf)</a>	
05/07/2014	SUPPL-48	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf)</a>	
05/07/2014	SUPPL-47	REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021071s047s048s049lbl.pdf)</a>	
05/30/2012	SUPPL-41	REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021071s041lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021071s041lbl.pdf)</a>	
11/13/2011	SUPPL-40	REMS-Modified	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s040lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s040lbl.pdf)</a>	
05/18/2011	SUPPL-39	REMS-Proposal	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s039lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s039lbl.pdf)</a>	
02/03/2011	SUPPL-38	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s038,021410s026,021700s010lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s038,021410s026,021700s010lbl.pdf)</a>	
10/20/2008	SUPPL-34	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s034lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s034lbl.pdf)</a>	
07/10/2008	SUPPL-26	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s026lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s026lbl.pdf)</a>	
02/22/2008	SUPPL-32	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s032lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s032lbl.pdf)</a>	
01/16/2008	SUPPL-29	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s029lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021071s029lbl.pdf)</a>	
11/14/2007	SUPPL-31	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s031lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s031lbl.pdf)</a>	
09/20/2007	SUPPL-27	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s027lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s027lbl.pdf)</a>	
08/14/2007	SUPPL-28	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s028lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s028lbl.pdf)</a>	
04/23/2007	SUPPL-23	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s023lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s023lbl.pdf)</a>	
06/16/2006	SUPPL-21	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf)</a>	
06/16/2006	SUPPL-19	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s019s021lbl.pdf)</a>	

Novo Nordisk Exhibit 2486

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/21/2006	SUPPL-16	Efficacy-Labeling Change With Clinical Data	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021071s016lbl.pdf</a> )	
07/29/2005	SUPPL-15	Efficacy-New Patient Population	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s015lbl.pdf</a> )	
05/12/2005	SUPPL-10	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s010lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021071s010lbl.pdf</a> )	
02/28/2005	SUPPL-12	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s012lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s012lbl.pdf</a> )	
01/04/2005	SUPPL-14	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s014lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21071s014lbl.pdf</a> )	
02/27/2003	SUPPL-4	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/021071s004lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/021071s004lbl.pdf</a> )	
04/03/2000	SUPPL-1	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia_prntlbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia_prntlbl.pdf</a> )	
05/25/1999	ORIG-1	Approval	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/21071lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/21071lbl.pdf</a> )	

Showing 1 to 28 of 28 entries