

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 021995
Company: MERCK SHARP DOHME

[EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021995\)](mailto:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021995)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf#page=27\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf#page=27)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm183768.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm183768.htm)

Products on NDA 021995

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
JANUVIA	SITAGLIPTIN PHOSPHATE	EQ 25MG BASE	TABLET;ORAL	Prescription	None	Yes	No
JANUVIA	SITAGLIPTIN PHOSPHATE	EQ 50MG BASE	TABLET;ORAL	Prescription	None	Yes	No
JANUVIA	SITAGLIPTIN PHOSPHATE	EQ 100MG BASE	TABLET;ORAL	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021995

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	Notes
10/16/2006	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021995lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/021995s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021995s000TOC.cfm)	

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/21/2022	SUPPL-50	Labeling-Medication Guide, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/021995Orig1s050_022044Orig1s052_202270Orig1s026ltr.pdf)	
12/04/2020	SUPPL-47	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021995s047lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/021995Orig1s047_022044Orig1s048_202270Orig1s022ltr.pdf)	
08/12/2019	SUPPL-45	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021995s045lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021995Orig1s045_202270Orig1s019_022044Orig1s046.ltr.pdf)	
07/01/2019	SUPPL-46	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021995s046lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021995Orig1s046_022044Orig1s047_202270Orig1s020ltr.pdf)	
02/09/2018	SUPPL-42	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021995s042lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/021995Orig1s042_022044s043_202270Orig1s018ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/10/2017	SUPPL-40	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021995s040lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/021995Orig1s040,022044Orig1s042,202270Orig1s017ltr.pdf)	
01/18/2017	SUPPL-38	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021995s038lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/021995Orig1s038ltr.pdf)	
01/11/2016	SUPPL-35	Manufacturing (CMC)		Label is not available on this site.
08/28/2015	SUPPL-34	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021995s034lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s034,022044Orig1s035,202270Orig1s010ltr.pdf)	
04/27/2015	SUPPL-33	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021995s033lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s033,022044Orig1s034,202270Orig1s009ltr.pdf)	
03/10/2015	SUPPL-32	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021995s032lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s032ltr.pdf)	
10/17/2013	SUPPL-28	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s028lbl.pdf)	
08/19/2013	SUPPL-29	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s029lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/021995Orig1s029ltr.pdf)	
02/11/2013	SUPPL-27	Labeling-Container/ Carton Labels, Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s027lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/021995Orig1s027ltr_replacement.pdf)	
12/07/2012	SUPPL-26	Manufacturing (CMC)		Label is not available on this site.
10/18/2012	SUPPL-25	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s025lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/021995Orig1s025ltr.pdf)	
03/24/2012	SUPPL-23	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s023lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/021995s023ltr.pdf)	
02/27/2012	SUPPL-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s019lbl.pdf)	
06/10/2011	SUPPL-16	Labeling-Container/ Carton Labels	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/019558s053plus15othersltr.pdf)	Label is not available on this site.
04/14/2011	SUPPL-17	Labeling, REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021995s017lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021995s017ltr.pdf)	
09/24/2010	SUPPL-18	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s015s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021995s015,s018ltr.pdf)	
09/24/2010	SUPPL-15	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s015s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021995s015,s018ltr.pdf)	
02/26/2010	SUPPL-14	Labeling-Medication Guide, REMS-Proposal	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021995s010s011s012s014ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021995orig1s014.pdf)	
02/26/2010	SUPPL-12	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021995s010s011s012s014ltr.pdf)	
02/26/2010	SUPPL-11	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021995s010s011s012s014ltr.pdf)	
02/26/2010	SUPPL-10	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/021995s010s011s012s014ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/28/2009	SUPPL-13	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021995s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021995s013ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/0219950rig1s013.pdf)	
10/20/2008	SUPPL-9	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021995s009ltr.pdf)	Label is not available on this site.
07/22/2008	SUPPL-7	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021995s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021995s007ltr.pdf)	
10/12/2007	SUPPL-6	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021995s002_s003_s004_s006ltr.pdf)	Label is not available on this site.
10/12/2007	SUPPL-4	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021995s002_s003_s004_s006ltr.pdf)	Label is not available on this site.
10/12/2007	SUPPL-3	Efficacy-Labeling Change With Clinical Data	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021995s002_s003_s004_s006ltr.pdf)	Label is not available on this site.
10/12/2007	SUPPL-2	Efficacy-Labeling Change With Clinical Data	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021995s002_s003_s004_s006ltr.pdf)	Label is not available on this site.
04/10/2007	SUPPL-1	Manufacturing (CMC)-Control		Label is not available on this site.

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New Drug Application (NDA): 021995

Company: MERCK SHARP DOHME

[EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021995\)](mailto:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021995)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf#page=27\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf#page=27)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm183768.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm183768.htm)

Products on NDA 021995 ▼

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021995 ▼

Labels for NDA 021995 ▲

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/21/2022	SUPPL-50	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf)	
06/21/2022	SUPPL-50	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021995s050lbl.pdf)	
12/04/2020	SUPPL-47	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021995s047lbl.pdf)	
08/12/2019	SUPPL-45	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021995s045lbl.pdf)	
07/01/2019	SUPPL-46	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021995s046lbl.pdf)	
02/09/2018	SUPPL-42	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021995s042lbl.pdf)	
08/10/2017	SUPPL-40	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021995s040lbl.pdf)	
01/18/2017	SUPPL-38	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021995s038lbl.pdf)	
08/28/2015	SUPPL-34	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021995s034lbl.pdf)	
04/27/2015	SUPPL-33	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021995s033lbl.pdf)	
03/10/2015	SUPPL-32	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021995s032lbl.pdf)	This supplement type does not usually require new labeling.
10/17/2013	SUPPL-28	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s028lbl.pdf)	This supplement type does not usually require new labeling.
08/19/2013	SUPPL-29	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s029lbl.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/11/2013	SUPPL-27	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s027lbl.pdf)	
02/11/2013	SUPPL-27	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021995s027lbl.pdf)	
10/18/2012	SUPPL-25	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s025lbl.pdf)	
03/24/2012	SUPPL-23	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s023lbl.pdf)	
02/27/2012	SUPPL-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s019lbl.pdf)	
04/14/2011	SUPPL-17	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021995s017lbl.pdf)	
04/14/2011	SUPPL-17	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021995s017lbl.pdf)	
09/24/2010	SUPPL-18	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s015s018lbl.pdf)	
09/24/2010	SUPPL-15	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s015s018lbl.pdf)	
02/26/2010	SUPPL-14	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf)	
02/26/2010	SUPPL-14	REMS-Proposal	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf)	
02/26/2010	SUPPL-12	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf)	
02/26/2010	SUPPL-11	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf)	
02/26/2010	SUPPL-10	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021995s010s011s012s014lbl.pdf)	
12/28/2009	SUPPL-13	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021995s013lbl.pdf)	
07/22/2008	SUPPL-7	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021995s007lbl.pdf)	
10/16/2006	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021995lbl.pdf)	

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