

# Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020741  
Company: GEMINI LABS LLC

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020741)

## Products on NDA 020741

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
PRANDIN	REPAGLINIDE	0.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
PRANDIN	REPAGLINIDE	1MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
PRANDIN	REPAGLINIDE	2MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 020741

### 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
12/22/1997	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/1997/020741s044lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/1997/020741s044lbl.pdf</a> )	

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### Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
01/22/2019	SUPPL-44	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020741s044lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020741s044lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/020741Orig1s044ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/020741Orig1s044ltr.pdf</a> )	
02/08/2017	SUPPL-42	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020741Orig1s041,s042ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020741Orig1s041,s042ltr.pdf</a> )	
02/08/2017	SUPPL-41	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020741Orig1s041,s042ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020741Orig1s041,s042ltr.pdf</a> )	
10/30/2015	SUPPL-43	Manufacturing (CMC)		Label is not available on this site.
03/01/2012	SUPPL-40	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020741s040lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020741s040lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/020741s040ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/020741s040ltr.pdf</a> )	
07/29/2010	SUPPL-38	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020741s038lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020741s038lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/020741s038ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/020741s038ltr.pdf</a> )	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/10/2009	SUPPL-35	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020741s035lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020741s035lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020741s035ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020741s035ltr.pdf</a> )	
07/14/2008	SUPPL-34	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020741s034lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020741s034lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/020741s034ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/020741s034ltr.pdf</a> )	
06/19/2006	SUPPL-30	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/020741s030LTR.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/020741s030LTR.pdf</a> ) Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/020741_s030_PRANDIN_TABS_AP.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/020741_s030_PRANDIN_TABS_AP.pdf</a> )	Label is not available on this site.
02/10/2005	SUPPL-22	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/20741s022lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/20741s022lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/20741s022ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/20741s022ltr.pdf</a> )	
10/15/2003	SUPPL-19	Manufacturing (CMC)-Packaging	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/20741scp019ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/20741scp019ltr.pdf</a> ) Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/020741_s019_PRANDIN_TABS_AP.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/020741_s019_PRANDIN_TABS_AP.pdf</a> )	Label is not available on this site.
08/27/2003	SUPPL-18	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20741slr018_prandin_lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20741slr018_prandin_lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/20741slr018ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/20741slr018ltr.pdf</a> )	
11/25/2002	SUPPL-16	Manufacturing (CMC)-Expiration Date	Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/020741_s016_PRANDIN_TABS_AP.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/020741_s016_PRANDIN_TABS_AP.pdf</a> )	Label is not available on this site.
10/21/2002	SUPPL-13	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s13lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s13lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/20741se1-013ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/20741se1-013ltr.pdf</a> )	
10/01/2002	SUPPL-15	Manufacturing (CMC)-Control	Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/020741_s015_PRANDIN_TABS_AP.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/020741_s015_PRANDIN_TABS_AP.pdf</a> )	Label is not available on this site.
08/05/2002	SUPPL-14	Manufacturing (CMC)-Expiration Date		Label is not available on this site.
01/18/2002	SUPPL-12	Efficacy-Labeling Change With Clinical Data	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s12lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s12lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/20741s12ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/20741s12ltr.pdf</a> )	
10/27/2000	SUPPL-10	Manufacturing (CMC)-Control		Label is not available on this site.
08/15/2000	SUPPL-9	Manufacturing (CMC)	Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/020741_s009_PRANDIN_TABS_AP.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/020741_s009_PRANDIN_TABS_AP.pdf</a> )	Label is not available on this site.
02/25/2000	SUPPL-8	Manufacturing (CMC)		Label is not available on this site.
12/08/1999	SUPPL-6	Manufacturing (CMC)		Label is not available on this site.
11/26/1999	SUPPL-7	Manufacturing (CMC)-Control		Label is not available on this site.
08/30/1999	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.
08/10/1999	SUPPL-1	Labeling		Label is not available on this site.
05/18/1999	SUPPL-4	Manufacturing (CMC)-Control		Label is not available on this site.
05/18/1999	SUPPL-3	Manufacturing (CMC)-Control		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
03/01/1999	SUPPL-2	Manufacturing (CMC)- Expiration Date		Label is not available on this site.

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**Labels for NDA 020741**



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New Drug Application (NDA): 020741

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[EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020741\)](mailto:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020741)

**Products on NDA 020741** ▼

**Approval Date(s) and History, Letters, Labels, Reviews for NDA 020741** ▼

**Labels for NDA 020741** ▲

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
01/22/2019	SUPPL-44	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020741s044lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020741s044lbl.pdf)</a>	
02/08/2017	SUPPL-42	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf)</a>	
02/08/2017	SUPPL-41	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020741s041s042lbl.pdf)</a>	
03/01/2012	SUPPL-40	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020741s040lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020741s040lbl.pdf)</a>	
07/29/2010	SUPPL-38	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020741s038lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020741s038lbl.pdf)</a>	
06/10/2009	SUPPL-35	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020741s035lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020741s035lbl.pdf)</a>	
07/14/2008	SUPPL-34	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020741s034lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020741s034lbl.pdf)</a>	
02/10/2005	SUPPL-22	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/20741s022lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/20741s022lbl.pdf)</a>	
08/27/2003	SUPPL-18	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20741s1r018_prandin_lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20741s1r018_prandin_lbl.pdf)</a>	
10/21/2002	SUPPL-13	Efficacy-New Indication	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s13lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s13lbl.pdf)</a>	
01/18/2002	SUPPL-12	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s12lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20741s12lbl.pdf)</a>	
12/22/1997	ORIG-1	Approval	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/1997/020741s044lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1997/020741s044lbl.pdf)</a>	

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