Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 017783
Company: PFIZER

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=017783)

Products on NDA 017783

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
GLUCOTROL	GLIPIZIDE	5MG	TABLET;ORAL	Discontinued	None	Yes	No
GLUCOTROL	GLIPIZIDE	10MG	TABLET;ORAL	Discontinued	None	Yes	No
GLUCOTROL	GLIPIZIDE	2.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No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 017783

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
05/08/1984	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD		Label is not available on this site.

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/18/2016	SUPPL-26	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/017783s026lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/017783Orig1s026ltr.pdf)**	
10/15/2013	SUPPL-25	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/017783s025lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/017783Orig1s025ltr.pdf)**	
02/07/2011	SUPPL-21	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/017783s021lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/017783s021ltr.pdf)**	
08/27/2009	SUPPL-20	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017783s020lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/017783s020ltr.pdf)**	
10/27/2008	SUPPL-19	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/017783s019lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/017783s019ltr.pdf)**	
12/15/1999	SUPPL-16	Manufacturing (CMC)-Packaging		Label is not available on this site.
08/06/1999	SUPPL-15	Labeling		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/11/1997	SUPPL-14	Manufacturing (CMC)		Label is not available on this site.
11/24/1993	SUPPL-13	Manufacturing (CMC)		Label is not available on this site.
05/19/1993	SUPPL-12	Labeling		Label is not available on this site.
05/11/1993	SUPPL-11	Manufacturing (CMC)-Formulation		Label is not available on this site.
08/06/1991	SUPPL-10	Manufacturing (CMC)		Label is not available on this site.
05/14/1987	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
03/31/1987	SUPPL-8	Labeling		Label is not available on this site.
03/04/1987	SUPPL-6	Manufacturing (CMC)-Packaging		Label is not available on this site.
09/15/1986	SUPPL-7	Manufacturing (CMC)		Label is not available on this site.
11/18/1985	SUPPL-4	Labeling		Label is not available on this site.
10/22/1985	SUPPL-3	Manufacturing (CMC)-Expiration Date		Label is not available on this site.
10/16/1985	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.
03/15/1985	SUPPL-2	Manufacturing (CMC)-Formulation		Label is not available on this site.

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Labels for NDA 017783

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Products on NDA 017783

Approval Date(s) and History, Letters, Labels, Reviews for NDA 017783

Labels for NDA 017783

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10/15/2013	SUPPL-25	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/017783s025lbl.pdf)**	
02/07/2011	SUPPL-21	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/017783s021lbl.pdf)**	
08/27/2009	SUPPL-20	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017783s020lbl.pdf)**	
10/27/2008	SUPPL-19	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/017783s019lbl.pdf)**	

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