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t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021845\)](https://twitter.com/intent/tweet?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=021845)



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New Drug Application (NDA): 021845

Company: PFIZER

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- [Patient Information Sheet \(http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021845s002PI.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021845s002PI.pdf)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/ucm390876.htm\)](http://www.fda.gov/Drugs/DrugSafety/ucm390876.htm)

Products on NDA 021845

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| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | RLD | TE Code |
|-----------|--------------------|--------------|-------------------|------------------|-----|---------|
| REVATIO | SILDENAFIL CITRATE | EQ 20MG BASE | TABLET;ORAL | Prescription | Yes | AB |

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021845

Original Approvals or Tentative Approvals**CSVExcelPrint**

| Action Date | Submission | Action Type | Submission Classification | Review Priority; Orphan Status | Letters, Reviews, Labels |
|--------------------|-------------------|--------------------|--|---------------------------------------|--|
| 06/03/2005 | ORIG-1 | Approval | Type 5 - New Formulation or New Manufacturer | PRIORITY | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/06/03/051212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2005/06/03/051212.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/review/2005/06/03/051212.pdf) |

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Supplements**CSVExcelPrint**

| Action Date | Submission | Submission Classification | Letters, Reviews, Labels, Patient Packages |
|--------------------|-------------------|---|---|
| 04/27/2015 | SUPPL-16 | Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/04/27/151212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/04/27/151212.pdf) |
| 02/03/2015 | SUPPL-9 | Manufacturing (CMC) | |
| 03/11/2014 | SUPPL-11 | Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/03/11/141212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/03/11/141212.pdf) |
| 03/06/2014 | SUPPL-14 | Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/03/06/141212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/02/18/141212.pdf) |
| 01/31/2014 | SUPPL-13 | Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/01/31/141212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/02/18/141212.pdf) |
| 01/31/2014 | SUPPL-12 | Efficacy- Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/01/31/141212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/02/18/141212.pdf) |
| 08/30/2012 | SUPPL-8 | Efficacy- Labeling Change With Clinical Data | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/08/30/121212.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/08/30/121212.pdf) |

| Action Date | Submission | Submission Classification | Letters, Review Patient Packa |
|-------------|------------|-----------------------------|---|
| 11/19/2010 | SUPPL-7 | Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/008481s07.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2010/008481s07.pdf) |
| 05/07/2009 | SUPPL-6 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/008481s06.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2009/008481s06.pdf) |
| 02/17/2009 | SUPPL-5 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/008481s05.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2009/008481s05.pdf) |
| 12/18/2007 | SUPPL-4 | Labeling | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/008481s04.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2007/008481s04.pdf) |
| 07/27/2006 | SUPPL-2 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2006/008481s02.pdf) |
| 07/19/2006 | SUPPL-3 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2006/008481s03.pdf) |
| 11/03/2005 | SUPPL-1 | Labeling | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appl/2005/008481s01.pdf) |

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Labels for NDA 021845 **Therapeutic Equivalents for NDA 021845** 