



[FDA Home](#)<sup>3</sup> [Drugs](#)<sup>4</sup> [Drug Approvals and Databases](#)<sup>5</sup> [Drugs@FDA](#)<sup>6</sup>

## Drug Approval Package

**Viagra (sildenafil citrate)**  
**Company: Pfizer**  
**Application No.: 020895**  
**Approval Date: 3/27/1998**

Persons with disabilities having problems accessing the PDF files below may call (301) 796-3634 for assistance.

- FDA's Clinical, Statistical and Biopharmacological Review of Viagra Clinical Development
  1. [Cover Sheet](#) (PDF) (3/27/1998)
  2. Joint Clinical Reviews (3/27/1998)
    - A. [Table of Contents](#) (PDF)
    - B. [Sections 1-6](#) (PDF)
    - C. [Section 7](#) (PDF)
    - D. [Section 8](#) (PDF)
    - E. [Section 9-10](#) (PDF)
    - F. [Appendix A, Sections 1-4](#) (PDF)
    - G. [Appendix A, Sections 5-9](#) (PDF)
    - H. [Appendix A, Sections 10-13](#) (PDF)
    - I. [Appendix A, Sections 14-22](#) (PDF)
    - J. [Appendix A, Sections 23-33](#) (PDF)
    - K. [Appendix A, Sections 34-43](#) (PDF)
    - L. [Appendix A, Sections 44-51](#) (PDF)
    - M. [Appendix A, Sections 52-56](#) (PDF)
  3. [Chemistry Review](#) (PDF) (3/27/1998)
  4. Pharmacology Reviews (3/27/1998)
    - A. [Review and Evaluation of Pharmacology and Toxicology Data, Pages 1-25](#) (PDF)
    - B. [Review and Evaluation of Pharmacology and Toxicology Data, Pages 26-48](#) (PDF)
    - C. [Review and Evaluation of Pharmacology and Toxicology Data, Pages 49-65](#) (PDF)
    - D. [Review and Evaluation of Pharmacology and Toxicology Data, Pages 66-90](#) (PDF)
    - E. [Review and Evaluation of Pharmacology and Toxicology Data, Pages 91-116](#) (PDF)
    - F. [Review and Evaluation of Pharmacology and Toxicology Data, Pages 117-142](#) (PDF)
  5. Statistical Carcinogenicity Reviews (3/27/1998)
    - A. [Carcinogenicity Review of Sildenafil in Rats and Mice](#) (PDF)
    - B. [Appendix A, Male Rats](#) (PDF)
    - C. [Appendix B, Female Rats](#) (PDF)
    - D. [Appendix C, Male Mice](#) (PDF)
    - E. [Appendix D, Female Mice](#) (PDF)
  6. [Carcinogenicity Assessment Committee and FDA/CDER Rodent Carcinogenicity Database Factsheet](#) (PDF) (3/27/1998)
  7. [Administrative Documents](#) (PDF) (3/27/1998)
  8. [Correspondence](#) (PDF) (3/27/1998)

Date created: March 27, 1998

[Back to Top](#) [Drugs@FDA](#)<sup>7</sup>

ATI 1019-0001

Vision impaired people having problems accessing certain pages of a PDF file may call (301) 796-3634 for assistance.

Note: Documents in PDF format require the [Adobe Acrobat Reader®](#)<sup>8</sup>.

---

**Links on this page:**

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/default.htm>
5. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
6. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
7. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
8. <http://get.adobe.com/reader/>

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewer and Players](#).

[Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Transparency Website Policies](#)



U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees Science & Research Regulatory Information Safety  
Emergency Preparedness International Programs News & Events Training and Continuing Education  
Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive](#)



U.S. Department of **Health & Human Services**

---

**Links on this page:**

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/default.htm>
5. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
6. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
7. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>
8. <http://get.adobe.com/reader/>