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Approval Package for:

Application Number: 020895

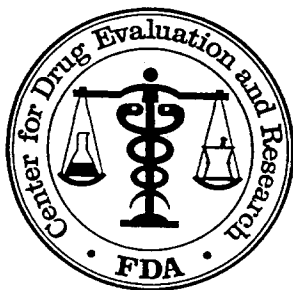
Trade Name: VIAGRA

Generic Name: Sildenafil Citrate

Sponsor: Pfizer

Approval Date: March 27,1998

FEB 2 1998



DIVISION OF CARDIO-RENAL DRUG PRODUCTS

Joint Clinical Review

NDA: 20-895 (Sildenafil for male impotence).

Sponsor: Pfizer Pharmaceuticals, Inc.

Submission:

Submission	NDA 20-757	
	Volumes	Received
Electronic data (pre-NDA)	—	15 Aug 1997
Original NDA submission	1.1-1.150	30 Sep 1997
Biopharmaceutics data		3 Nov 1997
Biopharmaceutics data		5 Nov 1997
Safety update	4.1-4.5	8 Dec 1997
Biopharmaceutics data		18 Dec 1997
Biopharmaceutics data		22 Dec 1997
Biopharmaceutics data		8 Jan 1998

Review date: 22 January 1998.

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Distribution: NDA 20-895 HFD-19 (FOI)
HFD-340/Viswanathan HFD-110 HFD-110/CSO
HFD-710/Mahjoob HFD-860/Marroum HFD-110/Stockbridge
HFD-710/Chi HFD-701/Anello
HFD-860/Malinowsky HFD-860/Mehta HFD-860/Parekh