CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:	**020895**
Trade Name:	**VIAGRA**
Generic Name:	**Sildenafil Citrate**
Sponsor:	**Pfizer**
Approval Date:	**March 27,1998**

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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

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Center for Drug Evaluation and Research

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Viagra (Sildenafil)

"Joint Clinical Review" for NDA-20-895

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