CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-895/S-001

Trade Name: Viagra

Generic Name: sildenafil citrate

Sponsor: Pfizer Pharmaceuticals Group

Approval Date: May 4, 1998

Indications: Provides for use of an additional manufacturing site for production of Viagra tablets.

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APPLICATION NUMBER:

20-895/S-001

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:

20-895/S-001

APPROVAL LETTER

NDA 20-895/ S-001

MAY - 4 1998

Pfizer Pharmaceuticals Group
Pfizer Inc.
Attention: Lana Liem
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Liem:

Please refer to your March 30, 1998 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viagra (sildenafil citrate) Tablets, 25, 50 and 100 mg.

The user fee goal date is September 30, 1998.

The supplemental application provides for the use of Pfizer Pharmaceuticals Inc. (PPI), Barceloneta, Puerto Rico, as an additional manufacturing site for production of Viagra tablets.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

5/1/98

James H. Short, Ph.D.
Acting Chemistry Team Leader, DNDC I
Division of Cardio-Renal Drug Products (HFD-110)
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: NDA 20-895/ S-001
HFD-110/ DIV FILE
HFD-110/ JAdvani 4/28/98
HFD-110/ Project Manager/ GBuehler
HFD-92
DISTRICT OFFICE
HFD-810/ CHoiberg
cg 4/28/98

Approval Date: March 27, 1998

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-895/S-001

CHEMISTRY REVIEW(S)

ORIGINAL

APR 2 9 1998

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 20-895
3. Name and Address of Applicant (City & State) Pfizer Pharmaceuticals Group Pfizer Inc 235 East 42nd Street New York, NY 10017-5755		4. Supplement(s) Number(s) Date(s) SCM-001 03/30/98
5. Drug Name Viagra	6. Nonproprietary Name Sildenafil citrate	7. Amendments & Other (reports, etc) - Dates
8. Supplement Provides For: Additional manufacturing site, Pfizer Pharmaceuticals Inc (PPI), in Barceloneta, Puerto Rico (PR). This is Changes Being Effected (CBE) supplement.		
9. Pharmacological Category	10. How Dispensed [X] Rx [ ] OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 25 mg, 50 mg, 100 mg	
14. Chemical Name and Structure		15. Records/Reports Current [ ] Yes [ ] No Reviewed [ ] Yes [ ] No

16. Comments

The production of Viagra tablets at the PPI, PR site complies with the CMC sections of the approved NDA. The manufacturing process is identical to the approved process at Brooklyn, NY site. This includes tablets compositions, equipment design, batch sizes, product testing and product release specifications.

Firm has submitted the batch records, testing data, 6* months accelerated and long term stability data and comparative multipoint dissolution data (refer review notes).

This CBE supplement for alternate facility is recorded in the EER system and Barceloneta, Puerto Rico site is acceptable

This supplement qualifies as a SUPAC-IR Level 3 site change and further the information provided is consistent with the agreements made at a meeting on 10/01/97 between agency and the firm.

17. Conclusions and Recommendations

The submission is recommended for approval. The approval letter is issued.

18. REVIEWER

Name JV Advani	Signature	Date Completed 04/22/98

Distribution:

[X] Original Jacket [X] Reviewer [X] Division File [X] CSO

jva/04/22/98/file# 20895S01

R/D init: JShort/

4/29/98

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confidential commercial

information from

Chemistry Review

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APPLICATION NUMBER:

20-895/S-001

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-895/S-001

APR 1 - 1998

Pfizer Pharmaceuticals Production Corporation Limited
c/o Pfizer Central Research
235 East 42nd Street
New York, NY 10017-5755

Attention: Lana Liem
Associate Director
Drug Regulatory Affairs

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Viagra (sildenafil citrate) Tablets

NDA Number: 20-895

Supplement Number: S-001

Date of Supplement: March 30, 1998

Date of Receipt: March 31, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 30, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation I
Attention: Document Control Room 5002
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA 20895/001
HFD-110/Div. Files
HFD-110/CSO/Gary Buehler

filename: C:\WPWIN61\TEMPLATE\FDA\20895S1.WPD

SUPPLEMENT ACKNOWLEDGEMENT

B.C.C.
3-31-98

4.1.98

ORIGINAL

Pfizer Pharmaceuticals Group
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 573 3833 Fax 212 573 1563

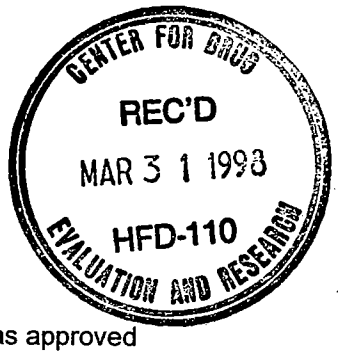
Pfizer Pharmaceuticals

Lana Liem
Associate Director
Drug Regulatory Affairs

March 30, 1998

Raymond Lipicky, M.D., Director
Division of Cardio-Renal
Drug Products (HFD-110)
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, Maryland 20852

NDA NO. 20-895 REF. NO. 001
NDA SUPPL FOR SCM



RE: Viagra (sildenafil citrate) Tablets, 25 mg, 50 mg, 100 mg
NDA #20-895
Changes Being Effected Supplement
Chemistry, Manufacturing and Controls

Dear Dr. Lipicky:

Please refer to NDA # 20-895 for 25 mg, 50 mg, 100 mg Viagra™ Tablets which was approved on March 27, 1998. In accordance with 21 CFR 314.70(a) and the SUPAC Guidance for Immediate Release Solid Oral Dosage Forms (November 1995), we are herein submitting a Changes Being Effected (CBE) supplement for an additional manufacturing site, Pfizer Pharmaceuticals Inc (PPI), located in Barceloneta, Puerto Rico. As agreed during a recent telephone conversation between Ms. Sandra Croak-Brossman, (Associate Director, Pfizer) and Mr. Gary Buehler, (Regulatory Health Product Manager), the Division of Cardio-Renal Drug Products will review this supplement.

The information that supports the additional site complies with all criteria detailed in the SUPAC Guidance under SITE CHANGES, Level 3. Furthermore, this supplement is consistent with the agreements made at a SUPAC meeting held on October 1, 1997 between Pfizer and FDA representatives; the meeting minutes are attached.

The production of Viagra™ tablets at the PPI site complies with the Chemistry, Manufacturing, and Controls sections of the approved NDA, and is identical to that in the approved Brooklyn, NY site. This includes tablet compositions, equipment design, batch sizes, product testing, and product release specifications. Minor differences in process parameters are summarized in Section IV. This supplement contains information on five Viagra™ tablet batches manufactured at PPI. The data indicate that the product manufactured at the alternate site meets all of the criteria approved in NDA # 20-895, and that the dissolution profiles of the NDA tablet batches made at the Brooklyn site are comparable to tablets made at PPI. Since there are no technical issues or concerns with this product, and PPI received a favorable GMP inspection on May 13-23, 1997, Pfizer believes that a CBE SUPAC supplement for this alternate manufacturing site is appropriate.

Pfizer plans to implement this site change and ship Viagra® tablets from the additional site on April 3, 1998. Please contact me at (212) 573-3833 with any questions.

Sincerely,

Lana Liem

Desk Copy: Dr. James Short
HFD-110 Room 5078
Woodmont Office Complex 2
Food and Drug Administration
1452 Rockville Pike
Rockville, MD 20852

Mr. Gary Buehler
HFD-110 Room 5025
Woodmont Office Complex 2
Food and Drug Administration
1452 Rockville Pike
Rockville, MD 20852

Mr. Edward Warner
District Director
New York District
Food and Drug Administration
850 Third Avenue
Brooklyn, NY 11232