CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 020895

ADMINISTRATIVE DOCUMENTS

690

REQUEST FOR TRADEMARK REVIEW

TO: Labeling and Nomenclature Committee
Attention: Dan Boring HFD-530

FROM: Division of: Cardio-Renal Drug Products HFD-110
Attention: Robert Wolters Phone: 594-5376

DATE: October 3, 1996

SUBJECT: Request for Assessment of a Trademark for a Proposed Drug Product

Proposed Trademark: Viagra NDA/ANDA IND 46,863

Company Name: Pfizer

Established name, including dosage form: Sildenafil Oral Tablets 50 and 100 mg

Other trademarks by the same firm for companion products:

Indications for Use (may be a summary if proposed statement is lengthy):
Oral therapy for male erectile dysfunction

Initial comments from the submitter: (concerns, observations, etc.)

Note: Meetings of the Committee are scheduled for the 4th Tuesday of the month. Please submit this form at least one week ahead of the meeting. Responses will be as timely as possible.

Rev. Dec.95

Consult #690 (HFD-110)

VIAGRA sildenafil oral tablets, 50 and 100 mg

There were no look-alike/sound-alike conflicts or misleading aspects noted with the proposed proprietary name. However, the Committee believes the non-proprietary name, sildenafil, has not been formally adopted yet by the United States Adopted Names Council. The Committee can only provide provisional acceptance of the proposed proprietary name pending final acceptance of the USAN name.

The Committee has no reason to find the proposed proprietary name unacceptable, pending final adoption of the non-proprietary name by the USAN Council.

P Y Boring 11/18/96, Chair
CDER Labeling and Nomenclature Committee

Note Sildenafil approve as USAN name 8-96.

Central Research Division
Pfizer Inc.
Eastern Point Road
Groton, CT 06340

Clinical Research

DATE: **February 10, 1998**

TO: **Mr. Gary Buehler**

FROM: **Dr. Sandra Croak-Brossman**

SUBJECT: **VIAGRA™, sildenafil citrate CAS name**

Question

The IUPAC name given by Pfizer for sildenafil citrate does not appear to be correct. The name given by Pfizer is:

1-[4-ethoxy-3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-d]pyrimidin-5-yl)phenylsulphonyl]-4-methylpiperazine citrate

We suggest that the CAS name is correct. The CAS name is given below:

1-{[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl}-4-methylpiperazine citrate

Response

At the time of filing, Pfizer believed that the name that we submitted was correct utilizing IUPAC guidelines. After further consideration of the IUPAC and the CAS guidelines, we now consider that the CAS name is preferable.

Therefore, we agree that the chemical name for sildenafil citrate is:

1-{[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl}-4-methylpiperazine citrate

and we will change the name in the product labeling to reflect this.

Question

What is the CAS number for sildenafil citrate?

Response

The CAS number for sildenafil citrate is 171599-83-0.

Question

Is Sildenafil Citrate the USAN name? If so, when was it adopted?

Response

Sildenafil citrate is the USAN and it was adopted by the USAN Council Aug. 1996. A copy of the Output from the USAN Electronic Database is given in Appendix 1.

Appendix 1

Output from the USAN Electronic Database

L1 ANSWER 1 OF 1 USAN COPYRIGHT 1998 USPC

Accession Number (AN): 1998:7242 USAN
Publication Year (PY): 1997
Generic Name (CN): ***Sildenafil Citrate***
OTHER NAMES:
Chemical Name (CN): ***(Sildenafil is INN and BAN)***
Chemical Name (CN): Piperazine, 1-((3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo(4,3-d)pyrimidin-5-yl)-4-ethoxyphenyl)sulfonyl)-4-methyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)
Chemical Name (CN): 1-((3-(6,7-Dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo(4,3- d)pyrimidin-5-yl)-4-ethoxyphenyl)sulfonyl)-4-methylpiperazine citrate (1:1)
Trade Name (CN): Viagra (Pfizer)
Code Designation (CN): UK-92,480-10
CAS Registry No. (RN): 171599-83-0; 139755-83-2 (sildenafil)
Lin. Str. Formula (LSF): C22 H30 N6 O4 S . C6 H8 O7
Molecular Weight (MW): 666.71
Classification (CC): Impotence therapy

USAN

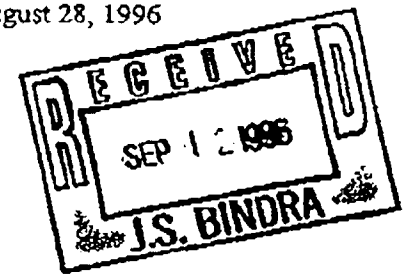
UNITED STATES ADOPTED NAMES COUNCIL

American Medical Association
515 North State Street
Chicago, Illinois 60610

Telefax: 312-464-4184
Telex: 280248 AMA CGO

SOPHIA V. FUERST, Assistant Secretary
(312) 464-5352

August 28, 1996



II-97

Pfizer Inc.
Central Research Division
Eastern Point Road
Groton, CT 06340

Attn: Jasjit S. Bindra, PhD
Senior Science Adviser

Dear Dr. Bindra:

It is my pleasure to inform you that the USAN Council adopted **sildenafil citrate** as the United States Adopted Name for UK-92,480-10; Viagra™, Pfizer Inc.'s selective inhibitor of cyclic GMP specific phosphodiesterase (Type V) with vasodilator action, used in the treatment of male erectile dysfunction.

Enclosed is a copy of the Statement of Adoption on **sildenafil citrate**. I plan to schedule publication of this information in the journal of Clinical Pharmacology and Therapeutics unless you request a delay within the next thirty days. Please use the enclosed statement to provide comments or additions. If this information is accurate, and may be published, please initial the statement and return it to me.

Sincerely yours,

Sophia V. Fuerst

Sophia V. Fuerst
Associate Secretary
USAN Council

SF

Enclosure: N96; 55

N96
55

August 28, 1996

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL:

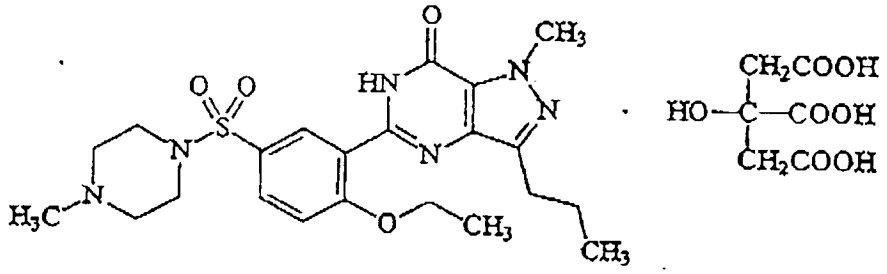
USAN (II-97)	SILDENAFIL CITRATE
PRONUNCIATION	sil de' na". fil
THERAPEUTIC CLAIM	treatment of male erectile dysfunction (selective inhibitor of cyclic GMP specific phosphodiesterase (Type V) with vasodilator action)

CHEMICAL NAMES

(1) 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)

(2) 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate (1:1)

STRUCTURAL FORMULA



MOLECULAR FORMULA	$C_{22}H_{30}N_6O_4S \cdot C_6H_8O_7$ or $C_{28}H_{38}N_6O_{11}S$
MOLECULAR WEIGHT	666.79
TRADEMARK	Viagra
MANUFACTURER	Pfizer Inc.
CODE DESIGNATION	UK-92,480-10
CAS REGISTRY NUMBER	171599-83-0
WHO NUMBER	7374

SF

USAN Council

List No. 397

New Names

The following nonproprietary names for the compounds described have been adopted by the United States Adopted Names (USAN) Council, which is sponsored by the American Medical Association, the American Pharmaceutical Association, and the US Pharmacopeial Convention, Inc., in cooperation with the respective pharmaceutical manufacturers. The designation USAN (United States Adopted Name) distinguishes these formally adopted nonproprietary names from other names. The information given under the category Therapeutic Claim is based on the manufacturer's claims at the time of publication. Adoption of USAN does not imply endorsement of the claims or products by the AMA, the US Pharmacopeia, or the APhA.

In some instances, the drugs listed are available only from the manufacturer to properly qualified investigators for clinical study.

Reprints of the *USAN Council New Names Column* are available at no charge by contacting: United States Adopted Names Council, American Medical Association, 515 North State Street, Chicago, IL 60610, (312) 464-4056.

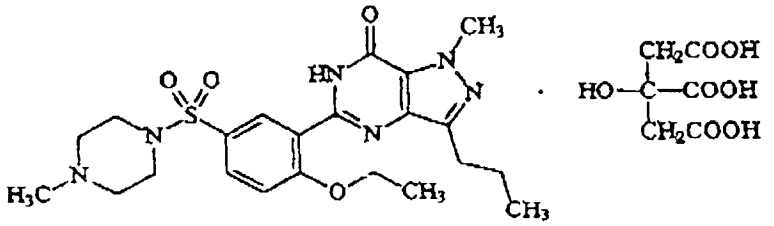
USAN	SILDENAFIL CITRATE
Pronunciation	sil de' na fil
Therapeutic claim	treatment of male erectile dysfunction (selective inhibitor of cyclic GMP specific phosphodiesterase (Type V) with vasodilator action)

Chemical names

(1) 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)

(2) 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazone citrate (1:1)

Structural formula



Molecular formula	$C_{22}H_{30}N_6O_4S \cdot C_6H_8O_7$ or $C_{28}H_{38}N_6O_{11}S$
Molecular weight	666.79
Trademark	Viagra
Manufacturer	Pfizer Inc.
Code designation	UK-92,480-10
CAS registry No.	171599-83-0
WHO No.	7374

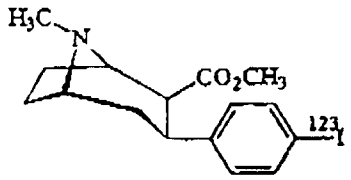
USAN	IOMETOPANE I 123
Pronunciation	eye oh me toh' pane
Therapeutic claim	diagnostic aid (in vivo diagnostic imaging of dopamine and serotonin transporter sites)

Chemical names

(1) methyl [1*R*-(*exo*,*exo*)]-3-[4-iodo-^{123}*I*)phenyl]-8-methyl-8-azabicyclo[3.2.1]octane-2-carboxylate

(2) methyl 3β-(*p*-[^{123}I]iodophenyl)-1αH,5αH-tropane-2β-carboxylate

Structural formula



Molecular formula	$C_{16}H_{20}{}^{123}INO_2$
Molecular weight	385.2
Trademark	Dopascan™ Injection
Manufacturer	Guilford Pharmaceuticals Inc.
Code designation	GPI-200
CAS registry No.	136794-86-0
WHO No.	7569

DRUG STUDIES IN PEDIATRIC PATIENTS
(To be completed for all NME's recommended for approval)

NDA # 20-895 Trade (generic) names Viagra (sildenafil) Tablets

Check any of the following that apply and explain, as necessary, on the next page:

__f__ 1. A proposed claim in the draft labeling is directed toward a specific pediatric illness. The application contains adequate and well-controlled studies in pediatric patients to support that claim.

____ 2. The draft labeling includes pediatric dosing information that is not based on adequate and well-controlled studies in children. The application contains a request under 21 CFR 210.58 or 314.126(c) for waiver of the requirement at 21 CFR 201.57(f) for A&WC studies in children.

____ a. The application contains data showing that the course of the disease and the effects of the drug are sufficiently similar in adults and children to permit extrapolation of the data from adults to children. The waiver request should be granted and a statement to that effect is included in the action letter.

____ b. The information included in the application does not adequately support the waiver request. The request should not be granted and a statement to that effect is included in the action letter. (Complete #3 or #4 below as appropriate.)

____ 3. Pediatric studies (e.g., dose-finding, pharmacokinetic, adverse reaction, adequate and well-controlled for safety and efficacy) should be done after approval. The drug product has some potential for use in children, but there is no reason to expect early widespread pediatric use (because, for example, alternative drugs are available or the condition is uncommon in children).

____ a. The applicant has committed to doing such studies as will be required.

____ (1) Studies are ongoing.
____ (2) Protocols have been submitted and approved.
____ (3) Protocols have been submitted and are under review.
____ (4) If no protocol has been submitted, on the next page explain the status of discussions.

____ b. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

__X__ 4. Pediatric studies do not need to be encouraged because the drug product has little potential for use in children.

____ 5. If none of the above apply, explain.

Explain, as necessary, the foregoing items: _____

/s/ Signature of Preparer

1/30/98
Date

cc: Orig NDA
HFD-__/Div File
NDA Action Package

13. PATENT AND EXCLUSIVITY INFORMATION FOR VIAGRA (SILDENAFIL CITRATE)

1.	Active Ingredient:	1-[4-ethoxy-3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1*H*-pyrazolo[4,3-d]pyrimidin-5-yl)phenylsulfonyl]-4-methylpiperazine citrate
2.	Strengths:	25, 50 and 100 mg
3.	Trade Name:	VIAGRA
4.	Dosage Form / Route of Administration:	Tablets / Oral
5.	Application Firm Name:	Pfizer Pharmaceuticals Production Corporation Ringaskiddy County Cork, Ireland
6.	NDA Number:	20-895
7.	Exclusivity Period:	5 years from the date of the approval of this application, as provided in FDCA Section 505 (j) (4) (D) (ii)
8.	Applicable Patent Numbers and Expiration Dates:	5,250,534 June 18, 2011

14. PATENT CERTIFICATION

With respect to the drug, VIAGRA™, which is the subject of this Application (NDA-20-895) and the U.S. patent which is listed in Section 13 of this Application, Pfizer certifies that the drug, VIAGRA™, and formulations thereof are claimed by U.S. Patent No. 5,250,534.