

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
200179Orig1s000

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

IND 57,703

Bayer HealthCare
Attention: William Cassano, Ph.D.
Global Regulatory Strategy Manager, Primary Care
P.O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Cassano:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Levitra® (vardenafil hydrochloride).

We also refer to your June 27, 2008, correspondence, received June 30, 2008, requesting a meeting to discuss [REDACTED] (b) (4)

On October 1, 2008, we provided our draft preliminary response to the questions presented in your September 4, 2008, meeting package. After receipt and review of this draft response, you informed the Division via telephone on October 2, 2008, that a meeting is not necessary at this time and you requested to cancel the meeting.

The final version of the Division's response is enclosed. You are responsible for notifying us of any significant differences in understanding.

If you have any questions, please call Eufrecina DeGuia Regulatory Health Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure - Memorandum of Meeting Communication

Memorandum of Meeting Communication

Scheduled Date of Meeting: October 6, 2008

Date Cancelled: October 2, 2008

IND 57,703

Drug Name: Levitra (vardenafil chloride)

Indication: treatment of erectile dysfunction

Sponsor's Question and Division's Response:

Regulatory

- 1. Does the Division concur that Bayer can cross-reference previously submitted clinical, nonclinical and clinical pharmacology data in the approved NDA 21-400?**

Answer: Yes. However, all relevant post-marketing safety data and study reports in support of the proposed label change should be submitted.

- 2. Does the Division agree to the proposed table of contents of the sNDA?**

Answer: No. An Integrated Summary of Safety, comparing safety in different age groups, (45 - 65 years, 65 – 75 years and >75 years) should be included in section 5.3.5.3.

- 3. Does the Division concur that there will be no user fee associated with the supplement since there is no new clinical data being submitted?**

Answer: No. The supplement will require the review of safety data (including previously submitted data or new data) for approval. User fee will be required.

[Please contact Mike Jones, User Fee Staff, Office of Regulatory Policy, at (301) 796-3602 for any questions.]

- 4. Has the Division identified any issues that would preclude filing of the supplement?**

Answer: No, but the decision to file will be determined after the initial review of the submission.

Labeling

(b) (4)

Clinical/Statistical

(b) (4)

- 2. Does the Division concur that Integrated Summaries of Safety and Efficacy will not be necessary since the submission will contain an analysis of data from studies that have been previously submitted to the Division?**

Answer: An Integrated Summary of Efficacy will not be needed.

(b) (4)

(See Answer to Question 2 under Regulatory)

Linked Applications

Sponsor Name

Drug Name

IND 57703

BAYER HEALTHCARE
PHARMACEUTICALS
INC

BAY 38-9456

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GEORGE S BENSON
10/08/2008



NDA 200179

NDA ACKNOWLEDGEMENT

Bayer Healthcare Pharmaceuticals
Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Park:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: (b) (4) (vardeafil hydrochloride), (b) (4)
10 mg (b) (4)

Date of Application: August 26, 2009

Date of Receipt: August 26, 2009

Our Reference Number: NDA 200179

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on October 25, 2009, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/cder/ddms/binders.htm>.

If you have any questions, please call me at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Eufrecina DeGuia
Regulatory Health Project Manager
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

EUFRECINA P DEGUIA
09/09/2009



NDA 200179

NDA ACKNOWLEDGEMENT

Bayer Healthcare Pharmaceuticals
Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Park:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: (b) (4) (vardenafil hydrochloride), 10 mg

Date of Application: August 26, 2009

Date of Receipt: August 26, 2009

Our Reference Number: NDA 200179

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on October 25, 2009, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/cder/ddms/binders.htm>.

If you have any questions, please call me at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Eufrecina DeGuia
Regulatory Health Project Manager
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICA LS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

EUFRECINA P DEGUIA
09/17/2009

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 9/28/09, 9/29/09, 9/30/09 voicemails

TO: Alexandra Park, Deputy Director, Global Regulatory Affairs
Bayer HealthCare Pharmaceuticals, Inc., Ph: 973-487-2026

THROUGH : Jeannie David, Regulatory Project Manager, ONDQA

FROM: Jeannie David, Regulatory Project Manager, ONDQA

SUBJECT: Memo of Telecon: Request for information on establishments information

APPLICATION/DRUG: NDA 200-179 / (b) (4) (vardenafil hydrochloride)

****Memo of Telecon:**

Information was requested in several voicemails from Jeannie David, RPM, ONDQA, to Alexandra Park, Bayer, regarding establishment information submitted to the original NDA on Form FDA 356h - Continuation Page: please submit fax numbers with the contact information for each establishment provided.

****Post Telecon Note:**

An email response to this request was received from the applicant on 10/01/09, attached.

David, Jeannie C

From: Alexandra Park [alexandra.park@bayer.com]
Sent: Thursday, October 01, 2009 9:10 AM
To: David, Jeannie C
Cc: catherine.tranzwametz@fda.hhs.gov; Deguia, Eufrecina P
Subject: NDA 200-179: Fax numbers for manufacturers
Attachments: 200-179 356h form continuation sheet_update.doc.zip

Dear Jeannie,

Thank you for your voice mail message - I was out of the office for the last two days so I apologize for not getting back to you sooner.

As per your request please find details of the fax numbers for the manufacturers detailed in our NDA application 200-179 submitted August 26, 2009.

This will additionally be submitted in an upcoming amendment submission to the eCTD NDA to replace the continuation sheet previously submitted .

Please don't hesitate to contact me if you require any additional information.

Many thanks and kind regards

Alex Park



Bayer HealthCare
Science For A Better Life

Bayer HealthCare Pharmaceuticals Inc.

GRA TA General Medicine

MONTVILLE

Phone: +1 973-487-2026

Fax: + 1 973-487-2016

Mobile: +1 862-221-2206

E-mail: alexandra.park@bayer.com

Web: <http://www.bayer.com>

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

10/1/2009

Bayer Schering Pharma AG
Friedrich-Ebert Str 217-333
42096 Wuppertal
Germany

ERN 3003229486

Drug Substance – All Steps

Contact Name: Klaus-Helmut Mohrs
Telephone Number +49 202 36 2307
Fax Number: +49 202-36 7612

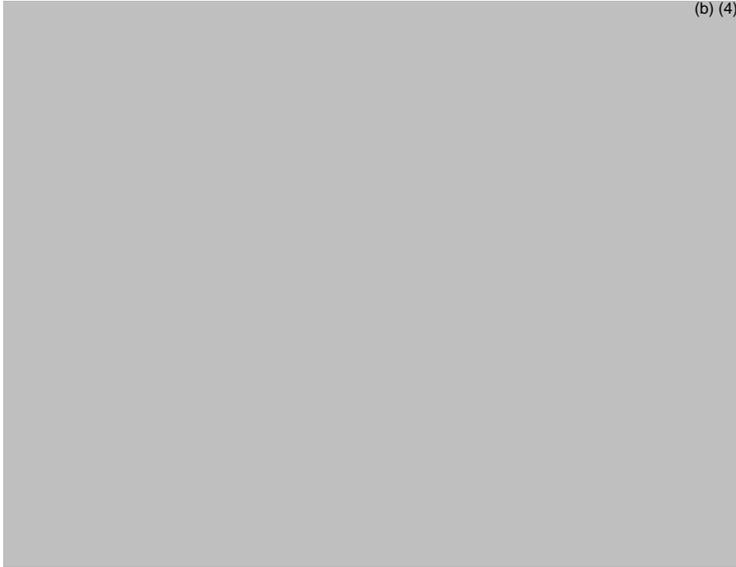
Bayer Schering Pharma AG
51368 Leverkusen
Germany

ERN 3002806462

Drug Product- All steps

Contact Name: Matthias Herboth
Telephone Number +49 214 30 57430
Fax Number: +49 214 30 61846

(b) (4)



Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-200179

ORIG-1

BAYER
HEALTHCARE
PHARMACEUTICA
LS INC

VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEANNIE C DAVID
10/05/2009



NDA 200179

FILING COMMUNICATION

Bayer Healthcare Pharmaceuticals
Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Park:

Please refer to your new drug application (NDA) dated and received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for vardenafil hydrochloride, 10 mg.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is Standard. Therefore, the user fee goal date is June 26, 2010.

During our filing review of your application, we identified the following potential review issues:

Chemistry, Manufacturing and Controls

1. Per 21 CFR 206.10, a code imprint is required on solid oral dosage forms. Add a code imprint to the dosage form or provide justification why an imprint is not provided.
2. The proprietary and established names on all labels should be updated as follows to reflect the dosage form:

TRADENAME (vardenafil hydrochloride) orally disintegrating tablets

3. As per 21 CFR 201.21(c), the following warning statement should be included on all package labeling. We note that it is included in the Physician Insert:

Phenylketonurics: Contains Phenylalanine (__)mg per tablet

4. Provide several samples of the drug product or placebo packaged in the to-be-marketed packaging, including the (b) (4) secondary packaging.

5. Submit updated stability data in the US container closure system by December, 2009, for review.

Office of New Drug Quality Assessment (ONDOQA)/Biopharmaceutics

1. Your proposal of using disintegration testing as a quality control test in lieu of dissolution is not acceptable for the following reasons:
 - Vardenafil hydrochloride does not appear to be a highly soluble substance. The ICH Q6A guidance outlines that disintegration may be substituted for dissolution if a product contains a drug which is highly soluble throughout the physiological range (dose/solubility volume < 250 mL from pH 1.2 to 6.8).
 - Information on [REDACTED] (b) (4) dissolution throughout the physiological pH was not been provided. Disintegration may be used in lieu of dissolution if the drug product is rapidly dissolving (dissolution >80% in 15 minutes at pH 1.2, 4.0 and 6.8).
 - The relationship between dissolution and disintegration has not been established.
2. Your claim in terms of [REDACTED] (b) (4) disintegration method being more discriminating than the dissolution method is inconclusive due to a lack of sufficient information (e.g. dissolution method development report and validation).

Based on the statements delineated in points 1 and 2, in addition to your proposed disintegration method, you are requested to develop a more discriminating dissolution method which will serve as a quality control test.

Statistical

The analysis and tabulation datasets are in one folder of the submission. They should be in separate folders, one for the analysis datasets and one for the tabulation datasets.

Clinical Pharmacology

Your proposal to revise the starting dose recommendation in elderly to 10 mg will be a review issue.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review. Issues may be added, deleted, expanded upon, or modified as we review the application. In addition, we also request that you submit the following information:

The bioanalytical method validation and sample analyses reports for the PK sub-study 12093 couldn't be located in the NDA. Submit this information or if already submitted, indicate its location in the NDA.

Please respond only to the above requests for additional information. While we anticipate that any response submitted in a timely manner will be reviewed during this review cycle, such review decisions will be made on a case-by-case basis at the time of receipt of the submission.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge receipt of your request for a full waiver of pediatric studies for this application.

If you have any questions, call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GEORGE S BENSON
10/23/2009



TELECONFERENCE MEETING MINUTES

NDA 200179

Bayer HealthCare Pharmaceuticals, Inc.
P.O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for [REDACTED] (b) (4) (Vardenafil Hydrochloride) Orally Disintegrating Tablets, 10 mg.

We also refer to the teleconference between representatives of your firm and the FDA on December 14, 2009. The purpose of the meeting was to discuss the review of the proposed proprietary name, [REDACTED] (b) (4).

A copy of the official minutes of the teleconference is attached for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Maria Wasilik, Safety Regulatory Project Manager, at (301) 796-0567.

Sincerely,

{See appended electronic signature page}

Denise P. Toyer, Pharm.D.
Deputy Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

MEMORANDUM OF TELECONFERENCE

Meeting Type: Type C
Meeting Category: Guidance

Meeting Date and Time: December 14, 2009 at 2:45 PM Eastern
Meeting Location: White Oak Conference Room 5440
Call in Number: 866-228-1482

Application Number: 200179
Product Name: (b) (4) (Vardenafil Hydrochloride)
Indication: Treatment of Erectile Dysfunction
Sponsor/Applicant Name: Bayer HealthCare Pharmaceuticals, Inc

Meeting Chair: Denise Toyer, FDA
Meeting Recorder: Maria Wasilik, FDA

FDA ATTENDEES

Office of Surveillance and Epidemiology

Maria Wasilik, Safety Regulatory Project Manager
Doris Bates, Team Leader, Project Management

Division of Medication Error Prevention and Analysis

Denise Toyer, Deputy Director
Todd Bridges, Team Leader
Jibril Abdus-Samad, Safety Evaluator

Division of Drug Marketing, Advertising and Communications

Cynthia Collins, Regulatory Review Officer

Division of Reproductive and Urologic Products

Eufrecina DeGuia, Regulatory Project Manager
Donald McNellis, MD, Medical Reviewer
Suresh Kaul, MD, MPH, Clinical Team Leader

Division of Clinical Pharmacology III, Office of Clinical Pharmacology

Sandhya Apparaju, PhD, Clinical Pharmacology Reviewer,

APPLICANT ATTENDEES

Alexandra Park, Deputy Director, Global Regulatory Affairs, Bayer Healthcare Pharmaceuticals Inc.
Janet Herrington, Vice President, Regulatory Affairs, Bayer Healthcare Pharmaceuticals Inc.
Donatella D'Urso, Regulatory Affairs, Bayer Schering Pharma AG
Abbey Abraham, Regulatory Affairs, Merck and Co, Inc.
Linda Rebar, Regulatory Affairs, GlaxoSmithKline Inc.
Tom Casola, Regulatory Affairs, Merck and Co Inc.

A. BACKGROUND

A request from Bayer Healthcare Pharmaceuticals, Inc., was submitted on October 30, 2009, for review for the proposed proprietary name, (b) (4), for Vardenafil Hydrochloride Orally Disintegrating Tablets. Vardenafil Hydrochloride is a phosphodiesterase type-5 inhibitor used in the treatment of erectile dysfunction. The Applicant currently markets Levitra (Vardenafil Hydrochloride) Tablets, which was approved on August 19, 2003.

FDA requested a teleconference with Bayer to discuss promotional and safety concerns with the proposed proprietary name, (b) (4).

B. DISCUSSION POINTS

The following promotional and safety concerns regarding the proposed proprietary name, (b) (4), were conveyed to the Applicant.

1. Promotional Concerns

(b) (4)

2. Safety Concerns

(b) (4)

FDA outlined the following two potential options with regards to the naming of the proposed product: (1) Bayer may propose a new proprietary name or (2) add a modifier to the existing proprietary name, Levitra, provided the sponsor submits data that supports the modifier conveys the difference between the existing Levitra product and the proposed product.

DRUP recommended that the Applicant consider having separate insert labeling for the currently marketed and the proposed Levitra products.

C. ACTION ITEMS

The Applicant stated that they will discuss internally and evaluate their alternative naming options then contact Maria Wasilik regarding their intentions.

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-200179

ORIG-1

BAYER
HEALTHCARE
PHARMACEUTICA
LS INC

VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DENISE P TOYER
01/21/2010



NDA 200179

**PROPRIETARY NAME REQUEST
UNACCEPTABLE**

Bayer HealthCare Pharmaceuticals, Inc.
P.O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) dated August 26, 2009, received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg.

We also refer to your October 30, 2009, correspondence, received October 30, 2009, requesting review of your proposed proprietary name, (b) (4). We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable for the following promotional reasons.

(b) (4)

Please note that the Federal Food Drug and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a proprietary name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience.

[21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i); (e)(6)(i)].

We recommend you consider the aforementioned concerns when selecting your alternate proprietary name and submit a new request for a proposed proprietary name review. (See the draft Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names*, and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Maria Wasilik, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0567. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Eufrecina Deguia at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICA LS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
01/28/2010



NDA 200179

GENERAL ADVICE

Bayer Healthcare Pharmaceuticals
Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Park:

Please refer to your new drug application (NDA) dated and received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for vardenafil hydrochloride, 10 mg.

We also refer to your December 8, 2009, submission, containing your response to our letter dated October 24, 2009, requesting that, in addition to your proposed disintegration method, you develop a more discriminating dissolution method which will serve as a quality control test.

The data provided in your submission dated Dec 8, 2009, indicate that disintegration testing is appropriate to discriminate changes in the process parameters or manufacturing conditions of (b) (4) Tablets, 10 mg. Specifically, disintegration values of (b) (4) seconds were observed for (b) (4) Tablets under (b) (4) compared to (b) (4) seconds under normal manufacturing conditions. Therefore, to ensure consistent quality of the drug product, we recommend the following disintegration specification for both, shelf-life and product release.

<u>Test</u>	<u>Specification</u>	
<u>Disintegration</u>	<u>Shelf-life Product</u>	<u>Release</u>
	(b) (4)	

If you have any questions, call Eufrecina DeGuia, Senior Regulatory Health Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chief, Branch III
Division of Pre-Marketing Assessment II
Office of New Drug Quality Assessment

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICA LS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MOO JHONG RHEE
03/24/2010
Chief, Branch III



NDA 200179

**PROPRIETARY NAME REQUEST
WITHDRAWN**

Bayer HealthCare Pharmaceuticals, Inc.
P.O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) dated August 26, 2009, received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg.

We acknowledge receipt of your April 20, 2010, correspondence, on April 21, 2010, notifying us that you are withdrawing your February 15, 2010 request for a review of the proposed proprietary name [REDACTED] ^{(b) (4)}. This proposed proprietary name request is considered withdrawn as of April 21, 2010.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5413. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Eufrecina Deguia at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
05/04/2010



NDA 200179

MEETING MINUTES

Bayer HealthCare Pharmaceuticals Inc.
P.O. Box 1000
Montville, New Jersey 07045-1000

Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for [REDACTED] (b) (4) (vardenafil hydrochloride) orally disintegrating tablets, 10 mg.

We also refer to the teleconference between representatives of your firm and the FDA on April 13, 2010. The purpose of the meeting was to discuss the review of the proposed proprietary name [REDACTED] (b) (4).

A copy of the official minutes of the teleconference is attached for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Karen Townsend, Safety Regulatory Project Manager, at (301) 796-5413.

Sincerely,

{See appended electronic signature page}

Kellie Taylor
Associate Director
Division of Medication Error Prevention and
Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

MEMORANDUM OF MEETING MINUTES

Meeting Type: Type C Meeting
Meeting Category: Guidance

Meeting Date and Time: April 13, 2010, 11:15 AM Eastern
Meeting Location: White Oak Conference Room 3376

Application Number: 200179
Product Name: (b) (4) (vardenafil hydrochloride)
Indication: treatment of erectile dysfunction
Applicant Name: Bayer HealthCare Pharmaceuticals, Inc

Meeting Chair: Kellie Taylor,
Meeting Recorder: Karen Townsend,

FDA ATTENDEES

Karen Townsend, Safety Regulatory Project Manager, Office of Surveillance and Epidemiology (OSE)
Kellie Taylor, Associate Director, Division of Medication Error Prevention and Analysis (DMEPA)
Todd Bridges, Team Leader, DMEPA
Jibril Abdus-Samad, Safety Evaluator, DMEPA
Donald McNellis, M.D., Medical Reviewer, Division of Reproductive and Urologic Products (DRUP)
Suresh Kaul, M.D., MPH, Medical Team Leader, DRUP

APPLICANT ATTENDEES

Alexandra Park, Regulatory Affairs, Bayer Healthcare Pharmaceuticals Inc.
Janet Herrington, Regulatory Affairs, Bayer Healthcare Pharmaceuticals Inc.
Donatella D'Urso, Regulatory Affairs, Bayer Schering Pharma AG
Abbey Abraham, Regulatory Affairs, Merck and Co, Inc.
Linda Rebar, Regulatory Affairs, GlaxoSmithKline Inc.
Albert Radlmaier, Global Clinical Development, Bayer Schering Pharma AG
Roland Heinig, Global Clinical Pharmacology, Bayer Schering Pharma AG
Jerry Phillips, President & CEO, Drug Safety Institute (DSI)
Nora Roselle, Managing Director, US Regulatory Affairs, DSI
Dyan Rowe Davis, Vice President, Safety Research, Brand Institute (BI)
Bill Johnson, President, US Eastern Division, BI
Max Wegner, Global Regulatory Affairs, Bayer Schering Pharma AG
Joachim Ippen, Global Project Manager, Bayer Schering Pharma AG

BACKGROUND

The Applicant initially proposed the proprietary name, [REDACTED] (b) (4), for this product. However, the name was found unacceptable for promotional concerns. These promotional concerns and additional safety concerns were discussed during the teleconference held on December 14, 2009, and communicated to the Applicant in a letter dated January 28, 2010.

In a letter, dated February 15, 2010, the Applicant requested review of the proposed proprietary names, [REDACTED] (b) (4) and [REDACTED] (b) (4), for Vardenafil orally disintegrating tablets, 10 mg. DMEPA requested this teleconference to discuss the proposed proprietary name review for [REDACTED] (b) (4) and [REDACTED] (b) (4).

1.0 SAFETY ISSUE WITH THE PROPOSED NAME, [REDACTED] (b) (4) AND [REDACTED] (b) (4)

[REDACTED] (b) (4)

2.0 DISCUSSION

[REDACTED] (b) (4)

The Applicant inquired if another proprietary name request for review was submitted, would it receive a decision from FDA prior to the PDUFA goal date of 6/26/2010. FDA explained that they would make the decision prior to the goal date.

FDA acknowledged that they took into consideration the safety data provided by the Applicant in their review.

FDA provided options to move the proprietary name process forward:

1. DMEPA can finalize the proprietary name review for (b) (4) and issue a decisional letter regarding your proposed proprietary name by 5/17/2010, the PDUFA goal date for tradename review.
2. The Applicant can withdraw their proprietary name request for (b) (4) and submit an alternate name for consideration.
 - a. If the Applicant wishes to retain the use of (b) (4) in the proprietary name, they should submit it with an alternate (b) (4).
 - b. If the Applicant wished to retain the (b) (4)

The name should clearly convey that the new dosage form is not a substitute for traditional LEVITRA tablets.

3.0 ISSUES REQUIRING FURTHER DISCUSSION

The Applicant understood the issues as presented, but they will need to evaluate alternative proposals and follow up with FDA regarding next steps. They understood the need for a separate and distinct trade name to distinguish between the two products.

4.0 ACTION ITEMS

The Applicant's representative will call Karen Townsend regarding next steps, after they have further internal discussions.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KELLIE A TAYLOR
05/19/2010

PEDIATRIC PAGE
(Complete for all filed original applications and efficacy supplements)

JA/BLA#: NDA 200179

Supplement Number: _____

NDA Supplement Type (e.g. SE5): _____

Division Name: Division of
Reproductive and Urologic
Products

PDUFA Goal Date: June 26,
2010

Stamp Date: 8/26/2009

Proprietary Name: _____ (b) (4)

Established/Generic Name: ildenafil hydrochloride

Dosage Form: 10 mg orodispersible tablet

Applicant/Sponsor: Bayer Healthcare Pharmaceuticals

Indication(s) previously approved (please complete this question for supplements and Type 6 NDAs only):

(1) treatment of erectile dysfunction

(2) _____

(3) _____

(4) _____

Pediatric use for each pediatric subpopulation must be addressed for each indication covered by current application under review. A Pediatric Page must be completed for each indication.

Number of indications for this pending application(s): _____

(Attach a completed Pediatric Page for each indication in current application.)

Indication: _____

1: Is this application in response to a PREA PMR? Yes Continue

No Please proceed to Question 2.

If Yes, NDA/BLA#: _____

Supplement #: _____

PMR #: _____

Does the division agree that this is a complete response to the PMR?

Yes. Please proceed to Section D.

No. Please proceed to Question 2 and complete the Pediatric Page, as applicable.

Q2: Does this application provide for (If yes, please check all categories that apply and proceed to the next question):

(a) NEW active ingredient(s) (includes new combination); indication(s); dosage form; dosing regimen; or route of administration?*

(b) No. PREA does not apply. **Skip to signature block.**

* **Note for CDER: SE5, SE6, and SE7 submissions may also trigger PREA.**

Q3: Does this indication have orphan designation?

Yes. PREA does not apply. **Skip to signature block.**

No. Please proceed to the next question.

Q4: Is there a full waiver for all pediatric age groups for this indication (check one)?

- Yes: (Complete Section A.)
 - No: Please check all that apply:
 - Partial Waiver for selected pediatric subpopulations (Complete Sections B)
 - Deferred for some or all pediatric subpopulations (Complete Sections C)
 - Completed for some or all pediatric subpopulations (Complete Sections D)
 - Appropriately Labeled for some or all pediatric subpopulations (Complete Sections E)
 - Extrapolation in One or More Pediatric Age Groups (Complete Section F)
- (Please note that Section F may be used alone or in addition to Sections C, D, and/or E.)

Section A: Fully Waived Studies (for all pediatric age groups)

Reason(s) for full waiver: (**check, and attach a brief justification for the reason(s) selected**)

- Necessary studies would be impossible or highly impracticable because:
 - Disease/condition does not exist in children
 - Too few children with disease/condition to study
 - Other (e.g., patients geographically dispersed): _____
- Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients AND is not likely to be used in a substantial number of pediatric patients.
- Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)

Justification attached.

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please complete another Pediatric Page for each indication. Otherwise, this Pediatric Page is complete and should be signed.

Section B: Partially Waived Studies (for selected pediatric subpopulations)

Check subpopulation(s) and reason for which studies are being partially waived (fill in applicable criteria below):

Note: If Neonate includes premature infants, list minimum and maximum age in "gestational age" (in weeks).

		Reason (see below for further detail):					
		minimum	maximum	Not feasible [#]	Not meaningful therapeutic benefit [*]	Ineffective or unsafe [†]	Formulation failed ^Δ
<input type="checkbox"/>	Neonate	__ wk. __ mo.	__ wk. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

Reason(s) for partial waiver (**check reason** corresponding to the category checked above, and **attach a brief**

justification):

.. Not feasible:

- Necessary studies would be impossible or highly impracticable because:
 - Disease/condition does not exist in children
 - Too few children with disease/condition to study
 - Other (e.g., patients geographically dispersed): _____

* Not meaningful therapeutic benefit:

- Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this/these pediatric subpopulation(s) AND is not likely to be used in a substantial number of pediatric patients in this/these pediatric subpopulation(s).

† Ineffective or unsafe:

- Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)

Δ Formulation failed:

- Applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for this/these pediatric subpopulation(s) have failed. (*Note: A partial waiver on this ground may only cover the pediatric subpopulation(s) requiring that formulation. An applicant seeking a partial waiver on this ground must submit documentation detailing why a pediatric formulation cannot be developed. This submission will be posted on FDA's website if waiver is granted.*)

Justification attached.

For those pediatric subpopulations for which studies have not been waived, there must be (1) corresponding study plans that have been deferred (if so, proceed to Sections C and complete the PeRC Pediatric Plan Template); (2) submitted studies that have been completed (if so, proceed to Section D and complete the PeRC Pediatric Assessment form); (3) additional studies in other age groups that are not needed because the drug is appropriately labeled in one or more pediatric subpopulations (if so, proceed to Section E); and/or (4) additional studies in other age groups that are not needed because efficacy is being extrapolated (if so, proceed to Section F). Note that more than one of these options may apply for this indication to cover all of the pediatric subpopulations.

Section C: Deferred Studies (for selected pediatric subpopulations).

Check pediatric subpopulation(s) for which pediatric studies are being deferred (and fill in applicable reason below):

Deferrals (for each or all age groups):				Reason for Deferral			Applicant Certification †
Population	minimum	maximum	Ready for Approval in Adults	Need Additional Adult Safety or Efficacy Data	Other Appropriate Reason (specify below)*	Received	
<input type="checkbox"/> Neonate	__ wk. __ mo.	__ wk. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> All Pediatric Populations	0 yr. 0 mo.	16 yr. 11 mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Date studies are due (mm/dd/yy): _____							

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

* Other Reason: _____

† Note: Studies may only be deferred if an applicant submits a certification of grounds for deferring the studies, a description of the planned or ongoing studies, evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time, and a timeline for the completion of the studies. If studies are deferred, on an annual basis applicant must submit information detailing the progress made in conducting the studies or, if no progress has been made, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time. This requirement should be communicated to the applicant in an appropriate manner (e.g., in an approval letter that specifies a required study as a post-marketing commitment.)

If all of the pediatric subpopulations have been covered through partial waivers and deferrals, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section D: Completed Studies (for some or all pediatric subpopulations).

Additional pediatric subpopulation(s) in which studies have been completed (check below):

Population		minimum	maximum	PeRC Pediatric Assessment form attached?	
<input type="checkbox"/>	Neonate	__ wk. __ mo.	__ wk. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/>	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

Note: If there are no further pediatric subpopulations to cover based on partial waivers, deferrals and/or completed studies, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section E: Drug Appropriately Labeled (for some or all pediatric subpopulations):

Additional pediatric studies are not necessary in the following pediatric subpopulation(s) because product is appropriately labeled for the indication being reviewed:

Population		minimum	maximum
<input type="checkbox"/>	Neonate	__ wk. __ mo.	__ wk. __ mo.
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/>	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

If all pediatric subpopulations have been covered based on partial waivers, deferrals, completed studies, and/or existing appropriate labeling, this Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section F: Extrapolation from Other Adult and/or Pediatric Studies (for deferred and/or completed studies)

Note: Pediatric efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations if (and only if) (1) the course of the disease/condition AND (2) the effects of the product are sufficiently similar between the reference population and the pediatric subpopulation for which information will be extrapolated. Extrapolation of efficacy from studies in adults and/or other children usually requires supplementation with other information obtained from the target pediatric subpopulation, such as

IF THERE ARE QUESTIONS, PLEASE CONTACT THE CDER PMHS VIA EMAIL (cderpms@fda.hhs.gov) OR AT 301-796-0700.

pharmacokinetic and safety studies. Under the statute, safety cannot be extrapolated.

pediatric studies are not necessary in the following pediatric subpopulation(s) because efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations:

Population		minimum	maximum	Extrapolated from:	
				Adult Studies?	Other Pediatric Studies?
<input type="checkbox"/>	Neonate	__ wk. __ mo.	__ wk. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	<input type="checkbox"/>	<input type="checkbox"/>

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

Note: If extrapolating data from either adult or pediatric studies, a description of the scientific data supporting the extrapolation must be included in any pertinent reviews for the application.

If there are additional indications, please complete the attachment for each one of those indications. Otherwise, this Pediatric Page is complete and should be signed and entered into DFS or DARRTS as appropriate after clearance by PeRC.

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

(Revised: 6/2008)

NOTE: If you have no other indications for this application, you may delete the attachments from this document.

Attachment A

(This attachment is to be completed for those applications with multiple indications only.)

.dication #2: _____

Q1: Does this indication have orphan designation?

- Yes. PREA does not apply. **Skip to signature block.**
- No. Please proceed to the next question.

Q2: Is there a full waiver for all pediatric age groups for this indication (check one)?

- Yes: (Complete Section A.)
- No: Please check all that apply:
- Partial Waiver for selected pediatric subpopulations (Complete Sections B)
 - Deferred for some or all pediatric subpopulations (Complete Sections C)
 - Completed for some or all pediatric subpopulations (Complete Sections D)
 - Appropriately Labeled for some or all pediatric subpopulations (Complete Sections E)
 - Extrapolation in One or More Pediatric Age Groups (Complete Section F)

(Please note that Section F may be used alone or in addition to Sections C, D, and/or E.)

Section A: Fully Waived Studies (for all pediatric age groups)Reason(s) for full waiver: (**check, and attach a brief justification for the reason(s) selected**)

- Necessary studies would be impossible or highly impracticable because:
- Disease/condition does not exist in children
 - Too few children with disease/condition to study
 - Other (e.g., patients geographically dispersed): _____
- Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients AND is not likely to be used in a substantial number of pediatric patients.
- Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are fully waived on this ground, this information must be included in the labeling.*)

 Justification attached.

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please complete another Pediatric Page for each indication. Otherwise, this Pediatric Page is complete and should be signed.

Section B: Partially Waived Studies (for selected pediatric subpopulations)

Check subpopulation(s) and reason for which studies are being partially waived (fill in applicable criteria below):
 Note: If Neonate includes premature infants, list minimum and maximum age in "gestational age" (in weeks).

		Reason (see below for further detail):					
		minimum	maximum	Not feasible [#]	Not meaningful therapeutic benefit [*]	Ineffective or unsafe [†]	Formulation failed ^Δ
<input type="checkbox"/>	Neonate	__ wk. __ mo.	__ wk. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

Reason(s) for partial waiver (**check reason** corresponding to the category checked above, and **attach a brief justification**):

Not feasible:

Necessary studies would be impossible or highly impracticable because:

- Disease/condition does not exist in children
- Too few children with disease/condition to study
- Other (e.g., patients geographically dispersed): _____

Not meaningful therapeutic benefit:

Product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this/these pediatric subpopulation(s) AND is not likely to be used in a substantial number of pediatric patients in this/these pediatric subpopulation(s).

† Ineffective or unsafe:

- Evidence strongly suggests that product would be unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)
- Evidence strongly suggests that product would be ineffective and unsafe in all pediatric subpopulations (*Note: if studies are partially waived on this ground, this information must be included in the labeling.*)

Δ Formulation failed:

Applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for this/these pediatric subpopulation(s) have failed. (*Note: A partial waiver on this ground may only cover the pediatric subpopulation(s) requiring that formulation. An applicant seeking a partial waiver on this ground must submit documentation detailing why a pediatric formulation cannot be developed. This submission will be posted on FDA's website if waiver is granted.*)

Justification attached.

For those pediatric subpopulations for which studies have not been waived, there must be (1) corresponding study plans that have been deferred (if so, proceed to Section C and complete the PeRC Pediatric Plan template); (2) submitted studies that have been completed (if so, proceed to Section D and complete the PeRC Pediatric Assessment form); (3) additional studies in other age groups that are not needed because the drug is appropriately labeled in one or more pediatric subpopulations (if so, proceed to Section E); and/or (4) additional studies in other age groups that are not needed because efficacy is being extrapolated (if so,

proceed to Section F).. Note that more than one of these options may apply for this indication to cover all of the pediatric subpopulations.

Section C: Deferred Studies (for some or all pediatric subpopulations).

Check pediatric subpopulation(s) for which pediatric studies are being deferred (and fill in applicable reason below):

Deferrals (for each or all age groups):				Reason for Deferral			Applicant Certification †
Population	minimum	maximum	Ready for Approval in Adults	Need Additional Adult Safety or Efficacy Data	Other Appropriate Reason (specify below)*	Received	
<input type="checkbox"/> Neonate	__ wk. __ mo.	__ wk. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/> All Pediatric Populations	0 yr. 0 mo.	16 yr. 11 mo.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Date studies are due (mm/dd/yy): _____							

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

* Other Reason: _____

† Note: Studies may only be deferred if an applicant submits a certification of grounds for deferring the studies, a description of the planned or ongoing studies, evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time, and a timeline for the completion of the studies. If studies are deferred, on an annual basis applicant must submit information detailing the progress made in conducting the studies or, if no progress has been made, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time. This requirement should be communicated to the applicant in an appropriate manner (e.g., in an approval letter that specifies a required study as a post-marketing commitment.)

If all of the pediatric subpopulations have been covered through partial waivers and deferrals, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section D: Completed Studies (for some or all pediatric subpopulations).

Additional pediatric subpopulation(s) in which studies have been completed (check below):

Population	minimum	maximum	PeRC Pediatric Assessment form attached?	
<input type="checkbox"/> Neonate	__ wk. __ mo.	__ wk. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<input type="checkbox"/> All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

Note: If there are no further pediatric subpopulations to cover based on partial waivers, deferrals and/or completed studies, Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

Section E: Drug Appropriately Labeled (for some or all pediatric subpopulations):

Additional pediatric studies are not necessary in the following pediatric subpopulation(s) because product is appropriately labeled for the indication being reviewed:

Population	minimum	maximum
<input type="checkbox"/> Neonate	__ wk. __ mo.	__ wk. __ mo.
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/> Other	__ yr. __ mo.	__ yr. __ mo.
<input type="checkbox"/> All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

If all pediatric subpopulations have been covered based on partial waivers, deferrals, completed studies, and/or existing appropriate labeling, this Pediatric Page is complete and should be signed. If not, complete the rest of the Pediatric Page as applicable.

ction F: Extrapolation from Other Adult and/or Pediatric Studies (for deferred and/or completed studies)

Note: Pediatric efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations if (and only if) (1) the course of the disease/condition AND (2) the effects of the product are sufficiently similar between the reference population and the pediatric subpopulation for which information will be extrapolated. Extrapolation of efficacy from studies in adults and/or other children usually requires supplementation with other information obtained from the target pediatric subpopulation, such as pharmacokinetic and safety studies. Under the statute, safety cannot be extrapolated.

Pediatric studies are not necessary in the following pediatric subpopulation(s) because efficacy can be extrapolated from adequate and well-controlled studies in adults and/or other pediatric subpopulations:					
Population		minimum	maximum	Extrapolated from:	
				Adult Studies?	Other Pediatric Studies?
<input type="checkbox"/>	Neonate	__ wk. __ mo.	__ wk. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other	__ yr. __ mo.	__ yr. __ mo.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	All Pediatric Subpopulations	0 yr. 0 mo.	16 yr. 11 mo.	<input type="checkbox"/>	<input type="checkbox"/>

Are the indicated age ranges (above) based on weight (kg)? No; Yes.

Are the indicated age ranges (above) based on Tanner Stage? No; Yes.

Note: If extrapolating data from either adult or pediatric studies, a description of the scientific data supporting the extrapolation must be included in any pertinent reviews for the application.

If there are additional indications, please copy the fields above and complete pediatric information as directed. If there are no other indications, this Pediatric Page is complete and should be entered into DFS or DARRTS as appropriate after clearance by PeRC.

This page was completed by:

{See appended electronic signature page}

Regulatory Project Manager

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT THE PEDIATRIC AND MATERNAL HEALTH STAFF at 301-796-0700

{Revised: 6/2008}

Degua, Eufrecina P

From: Greeley, George
Sent: Tuesday, June 01, 2010 11:49 AM
To: Degua, Eufrecina P
Cc: McNellis, Donald; Kaul, Suresh; Stowe, Ginneh D.
Subject: RE: NDA 200179 (b) (4) (orodispersible tablet) - PEDIATRIC PAGE

Thanks for the clarification Freshnie!

Please ignore my email about it triggering PREA then. We will record this one as PREA does not apply. You may proceed with your approval action as mentioned earlier.

Thanks!
George

From: Degua, Eufrecina P
Sent: Tuesday, June 01, 2010 11:46 AM
To: Greeley, George
Cc: McNellis, Donald; Kaul, Suresh
Subject: RE: NDA 200179 (b) (4) (orodispersible tablet) - PEDIATRIC PAGE

Hi George,

Thank you for your response. This product does not get an orphan designation. It's for the treatment of erectile dysfunction same as Viagra, Cialis and Levitra (same drug).

FYI. This is NOT a new dose form. It's still a tablet, just a different formulation (orodispersible, does not need water).

Please let me know if you have any questions. I cc'd the clinical team so they are aware of the status.

Sincerely,
Freshnie

From: Greeley, George
Sent: Tuesday, June 01, 2010 11:37 AM
To: Degua, Eufrecina P
Subject: RE: NDA 200179 (b) (4) (orodispersible tablet) - PEDIATRIC PAGE

Hi Freshnie,

My apologies for not responding sooner. From what I can tell this product would trigger PREA as a new dosage form. I took it that this was a product receiving orphan designation as most of yours are it seems.

The Division can take an action prior to the PeRC reviewing since the indication is one that would warrant a full waiver. We will schedule this for PeRC review at our next opening for which the materials would be needed. The Division does not have to attend the review in person.

Again sorry for the mishap.

Thanks,
George

From: Degua, Eufrecina P
Sent: Tuesday, June 01, 2010 11:09 AM
To: Greeley, George
Subject: FW: NDA 200179 (b) (4) (orodispersible tablet) - PEDIATRIC PAGE

Hi George,

This is a follow up. Please see email below. We plan to take action on June 18th. Please let me know if you need anything else.

I look forward to hearing from you.

Sincerely,
Freshnie

From: Deguia, Eufrecina P
Sent: Monday, April 05, 2010 9:59 AM
To: Greeley, George
Subject: NDA 200179 (b) (4) (orodispersible tablet) - PEDIATRIC PAGE

Hi George,

I apologize for not sending this pediatric page to you sooner. FYI. Levitra (vardenafil hydrochloride) is approved for the treatment of erectile dysfunction. This new NDA 200179 is for a new formulation (orodispersible tablet). The approved Levitra is immediate release tablet. << File: NDA 200179 (b) (4) (b) (4) Peditaric Page.doc >>

Let me know if you need anything else.

Thank you so much for your time.

Sincerely,

Freshnie

*Freshnie DeGuia
Regulatory Project Manager
Division of Reproductive and Urologic Products
Center for Drug Evaluation and Research
Food and Drug Administration
Phone: (301) 796-2130 (main)
Direct Line: (301) 796-0881
Fax: (301) 796-9897
Email: eufrecina.deguia@fda.hhs.gov*



NDA 200179

GENERAL ADVICE

Bayer Healthcare Pharmaceuticals
Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Park:

Please refer to your new drug application (NDA) dated and received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for vardenafil hydrochloride orally disintegrating tablet (ODT), 10 mg.

We are reviewing your application and have determined that a postmarketing clinical trial will be required, if this application is approved. We request that you provide a timetable for conducting the postmarketing requirement (PMR) listed below. We request a prompt written response in order to continue our evaluation of your NDA.

Drug interaction study to assess the potential for orthostatic hypotension in elderly men (age 65 – 80) with erectile dysfunction on vardenafil hydrochloride ODT, 10 mg, whose hypertension is under control with a vasodilator who have been on a stable dose for at least four weeks. The design should be a randomized, double-blind, placebo-controlled, cross-over study stratified by age (n=20 in age 65-69, n=20 in age 70-80) with the following treatments: vardenafil 10 mg ODT or placebo administered concomitantly with a vasodilator. Blood pressure and heart rate should be measured 1 hour prior to administration of vardenafil and hourly for 10 hours following dosing. These measurements should be taken after being supine for 10 minutes, then after sitting for one minute, then after standing for five minutes.

Timelines to be provided:

Final Protocol Submission:

Study Completion Date:

Final Report Submission:

If you have any questions, call Eufrecina DeGuia, Senior Regulatory Health Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GEORGE S BENSON
06/08/2010



NDA 200179

TELECONFERENCE MEETING MINUTES

Bayer HealthCare Pharmaceuticals Inc.
P.O. Box 1000
Montville, New Jersey 07045-1000

Attention: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for (b) (4) (vardenafil hydrochloride) orally disintegrating tablets, 10 mg.

We also refer to the teleconference between representatives of your firm and the FDA on May 27, 2010. The purpose of the meeting was to discuss the review of the proposed proprietary name (b) (4)

A copy of the official minutes of the teleconference is attached for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Karen Townsend, Safety Regulatory Project Manager, at (301) 796-5413.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Team Leader
Division of Medication Error Prevention and
Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

MEMORANDUM OF MEETING MINUTES

Meeting Type: Type C Meeting
Meeting Category: Guidance

Meeting Date and Time: May 27, 2010, 2:45 PM Eastern
Meeting Location: White Oak Conference Room 5313

Application Number: 200179
Product Name: (b) (4) (vardenafil hydrochloride)
Indication: treatment of erectile dysfunction
Applicant Name: Bayer HealthCare Pharmaceuticals, Inc

Meeting Chair: Todd Bridges
Meeting Recorder: Karen Townsend

FDA ATTENDEES

Denise Toyer, Deputy Director, Division of Medication Error Prevention and Analysis (DMEPA)
Todd Bridges, Team Leader, DMEPA
Jibril Abdus-Samad, Safety Evaluator, DMEPA
Donald McNellis, M.D., Medical Reviewer, Division of Reproductive and Urologic Products (DRUP)
Suresh Kaul, M.D., MPH, Medical Team Leader, DRUP
Karen Townsend, Safety Regulatory Project Manager, Office of Surveillance and Epidemiology (OSE)
Doris Bates, Team Leader, Project Management, OSE

APPLICANT ATTENDEES

Alexandra Park, Regulatory Affairs, Bayer Healthcare Pharmaceuticals Inc.
Janet Herrington, Regulatory Affairs, Bayer Healthcare Pharmaceuticals Inc.
Donatella D'Urso, Regulatory Affairs, Bayer Schering Pharma AG
Abbey Abraham, Regulatory Affairs, Merck and Co, Inc.
Linda Rebar, Regulatory Affairs, GlaxoSmithKline Inc.
Jim Bammert, Regulatory Affairs, Merck and Co, Inc.

BACKGROUND

The Applicant initially proposed the proprietary name, (b) (4), for this product. However, the name was found unacceptable for promotional concerns. These promotional concerns and additional safety concerns were discussed during a teleconference held on December 14, 2009, and communicated to the Applicant in a letter dated January 28, 2010. In a subsequent letter, dated February 15, 2010, the Applicant requested review of the proposed proprietary names, (b) (4) and (b) (4), for Vardenafil orally disintegrating tablets, 10 mg. A teleconference was held on April 13, 2010, to discuss safety issues with the proposed

proprietary names (b) (4) and (b) (4). These concerns were also communicated to the Applicant in a letter dated May 19, 2010.

The applicant subsequently proposed a new proprietary name, (b) (4) in a letter dated April 20, 2010. This letter also included an alternative proprietary name, (b) (4) DMEPA requested this teleconference to discuss results of the proprietary name review for the proposed name, (b) (4)

1.0 SAFETY ISSUE WITH THE PROPOSED NAME, (b) (4)

In our assessment of the proposed proprietary name, (b) (4) we identified that the name (b) (4) is vulnerable to name confusion with the name (b) (4) due to orthographic similarities and similar product characteristics. The table below lists the similarities.

(b) (4)

(b) (4) and (b) (4) share the same strength (10 mg) and the dosing frequency (once daily). We acknowledge (b) (4) is mostly prescribed as a twice daily drug; however, it is also prescribed with once daily administration. Additionally, post-marketing experience demonstrates that differences in frequency of administration are minimal at decreasing medication errors when product names are very similar. Furthermore, (b) (4) is available in a Titration Pack and (b) (4) has a proposed (b) (4) Pack. Prescriptions for both of these packaging configurations may contain the instructions 'use as directed'. Thus, giving the orthographic similarity with the two product names and the similar product characteristics, there is increased risk of confusion that could result in a medication error between (b) (4) and (b) (4). Therefore, FDA finds the proposed name for this product, (b) (4), unacceptable.

2.0 DISCUSSION

The safety concerns that were presented by DMEPA for the proposed proprietary name were discussed. Options were discussed on steps forward with the proprietary name review.

As noted, the Bayer submitted the name, (b) (4) as an alternate name when (b) (4) was submitted. An initial review process has begun on (b) (4). However, for formal review to continue, Bayer needs to formally withdraw the currently proposed name, (b) (4) and submit a request for proprietary name review for the alternate proposed name, (b) (4). FDA explained that since the time frames are close to the OND PDUFA goal date of June 23, 2010, we need to know for certain that (b) (4) is the Applicant's choice for the proposed proprietary name. With the goal date being so close, there will not be sufficient time to review any additional names subsequent to the review of (b) (4) (or your alternate proposed name) before the OND PDUFA date.

Bayer indicated that they had analysis and testing from external studies for (b) (4) but not for other names at this time. FDA indicated that it is not a requirement to have an external study. Additionally, FDA emphasized that we were not dissuading Bayer from proposing the alternative name, (b) (4).

The Applicant agreed to contact Karen Townsend, by close of business, Tuesday, June 1, 2010, with their decision on either proceeding ahead with review for the alternate proposed name (b) (4) and withdrawing (b) (4) or submitting a different proposed proprietary name, and withdrawing (b) (4).

3.0 ISSUES REQUIRING FURTHER DISCUSSION

The Applicant understood the issues as presented, but they will need to have an internal discussion before determining their next step.

4.0 ACTION ITEMS

As noted above, the Applicant's representative will call Karen Townsend, by close of business June 1, 2010, to communicate their decision on whether to formally request a review of (b) (4) or submit another name for review, after further internal discussions.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TODD D BRIDGES
06/11/2010



NDA 200179

**PROPRIETARY NAME REQUEST
WITHDRAWN
ACKNOWLEDGE SUBMISSION OF
NEW PROPRIETARY NAME**

Bayer HealthCare Pharmaceuticals, Inc.
P. O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) dated August 26, 2009, received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg.

We acknowledge receipt of your June 2, 2010, correspondence on June 2, 2010, notifying us that you are withdrawing your request for a review of the proposed proprietary name, (b) (4). This proposed proprietary name request is considered withdrawn as of June 2, 2010.

We also acknowledge receipt of your June 2, 2010, correspondence on June 2, 2010, requesting a review of your proposed proprietary name, Staxyn.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5413. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Eufrecina Deguia, at (301) 796-0881.

Sincerely,
{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
06/11/2010

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: June 10, 2010

TO: FILE

THROUGH : N/A

FROM: Freshnie DeGuia, Senior Regulatory Health Project Manager

SUBJECT: Division of Medication Error Prevention and Analysis (DMEPA) Comments

APPLICATION/DRUG: NDA 200179 - vardenafil hydrochloride orally disintegrating tablet (ODT)

The purpose of this Memorandum to File is to document the comments sent to Alexandra Park, Deputy Director, Bayer Healthcare Pharmaceuticals, via email on June 10, 2010 regarding the comments from DMEPA regarding carton and container labeling.

Please refer to DMEPA's review dated June 9, 2010 in DARRTS.

Additional recommendations from DMEPA regarding carton and container labeling:

A. General Comment

1. The proposed proprietary name, Staxyn, is currently under review by DMEPA. The container labels and carton labeling bear this proposed proprietary name, therefore the labels and labeling for this product are not acceptable for marketing bearing this proposed proprietary name.
2. Clarify which manufacturer, distributor or marketing entity patients and healthcare providers must contact for inquiries or to report adverse events for your product. There are multiple companies present on the carton labeling without clear indication of who receives correspondence for your product.

B. All Blister Container Labels

Revise the dosage form statement from ‘orally disintegrating tablets’ to read ‘orally disintegrating tablet’ since there is only one tablet contained in each unit dose blister.

C. Sample Blister Container Labels

1. Relocate the strength to appear after the dosage form. As currently presented, the strength is located between the established name and dosage form. Thus, the statement should read as follows:

Staxyn
(vardenafil hydrochloride)
orally disintegrating tablet 10 mg

2. Delete the graphic of what appears as a crossed out tablet. It is unclear what this graphic represents and may lead to confusion. Consider substituting the graphic with a statement to convey your intended message.

D. All Carton Labeling

1. Ensure the established name is at least ½ the size of the proprietary name taking into account all pertinent factors, including typography, layout, contrast, and other printing features in accordance with 21 CFR 201.10(g)(2).
2. Decrease the prominence of the quantity of tablets and increase the prominence of the strength. As currently presented, the quantity of tablets has more prominence than the product strength. The product strength is more important than the quantity in regards to identifying the correct drug product and thus must be more prominent.
3. Revise the statement ‘DOSAGE: Take one tablet as needed’ to read ‘USUAL DOSAGE: Take on tablet as needed.’

E. Sample Carton Labeling (2 tablets) and Carton Labeling (4 tablet tablets)

1. Revise the strength statement to read 10 mg per tablet since this product will be a unit dose blister pack. As currently presented, patients may potentially conclude all the tablets in the package are needed to achieve the 10 mg dose.
2. Include the product strength on the side panel attached to the principal display panel.
3. Relocate the two schematics and associated text that instruct patients to place Staxyn on the tongue and take Staxyn without liquid from its current location to directly below the strength. This improves readability of the labeling and decreases crowding of information.

F. Sample Carton Labeling

Decrease the prominence of the statement 'Professional sample. Not for sale' and relocate it to another space on the principle display panel to make room for the two schematics and associated text that instruct patients to place Staxyn on the tongue and take Staxyn without liquid.

G. Carton Labeling (4 tablets)

Delete the statement *Staxyn Pack*. *Staxyn Pack* appears to be a proprietary name of a pack configuration; however, *Staxyn* was submitted for review as a proprietary name for this product.

H. Carton Labeling (40 tablets)

Include the product strength on the rear panel after the dosage form statement.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICA LS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

EUFRECINA P DEGUIA
06/14/2010

Bates, Doris J

From: Bates, Doris J
Sent: Tuesday, June 15, 2010 12:53 PM
To: 'Alexandra Park'
Cc: Townsend, Karen; Bates, Doris J
Subject: RE: NDA 200179 (vardenafil hydrochloride orally disintegrating tablets, 10 mg): Proposed Proprietary Name Staxyn
Importance: High

Dear Ms. Park:

I have been authorized to inform you that the Division of Medication Error Prevention and Analysis, in the Office of Surveillance and Epidemiology at FDA, has found your proposed proprietary name, Staxyn, acceptable for the above referenced drug product.

We will be sending formal correspondence to this effect within the next few days.

Please contact the Office of New Drugs Regulatory Project Manager, Eufrecina Deguia, at (301)-796-0881 if you have questions regarding the NDA. Please contact either myself or Karen Townsend, Safety Regulatory Project Manager, Office of Surveillance and Epidemiology, at (301)-796-5413, if you have any questions regarding this message or any aspect of the proprietary name review process.

Sincerely,

Doris J. Bates, Ph.D

*Doris J. Bates, Ph.D.
Team Leader -- Project Management Staff
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research
Phone: 301-796-1040; Fax: 301-796-9721, -9725
Email: doris.bates@fda.hhs.gov*

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-200179

ORIG-1

BAYER
HEALTHCARE
PHARMACEUTICA
LS INC

VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DORIS J BATES
06/15/2010



NDA 200179

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Bayer HealthCare Pharmaceuticals, Inc.
P. O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) dated August 26, 2009, received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg.

We also refer to your June 2, 2010, correspondence, received June 2, 2010, requesting review of your proposed proprietary name, Staxyn. We have completed our review of the proposed proprietary name, Staxyn, and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your June 2, 2010, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5413. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Eufrecina Deguia, at (301) 796-0881.

Sincerely,
{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-200179

ORIG-1

BAYER
HEALTHCARE
PHARMACEUTICA
LS INC

VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
06/16/2010



NDA 200179

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Bayer HealthCare Pharmaceuticals, Inc.
P. O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) dated August 26, 2009, received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg.

We also refer to your June 2, 2010, correspondence, received June 2, 2010, requesting review of your proposed proprietary name, Staxyn. We have completed our review of the proposed proprietary name, Staxyn, and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your June 2, 2010, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5413. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Eufrecina Deguia, at (301) 796-0881.

Sincerely,
{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-200179

ORIG-1

BAYER
HEALTHCARE
PHARMACEUTICA
LS INC

VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
06/16/2010



NDA 200179

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Bayer HealthCare Pharmaceuticals, Inc.
P. O. Box 1000
Montville, New Jersey 07045-1000

ATTENTION: Alexandra Park
Deputy Director, Global Regulatory Affairs

Dear Ms. Park:

Please refer to your New Drug Application (NDA) dated August 26, 2009, received August 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg.

We also refer to your June 2, 2010, correspondence, received June 2, 2010, requesting review of your proposed proprietary name, Staxyn. We have completed our review of the proposed proprietary name, Staxyn, and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your June 2, 2010, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5413. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Eufrecina Deguia, at (301) 796-0881.

Sincerely,
{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-200179

ORIG-1

BAYER
HEALTHCARE
PHARMACEUTICA
LS INC

VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
06/16/2010

EXCLUSIVITY SUMMARY

NDA # 200179

SUPPL #

HFD #

Trade Name STAXYN

Generic Name (vardenafil hydrochloride) orally disintegrating tablet

Applicant Name Bayer Healthcare Pharmaceuticals

Approval Date, If Known June 17, 2010

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3, SE4, SE5, SE6, SE7, SE8

Type 3 NDA - new formulation

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

3 years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

No

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 21-400

Levitra (vardenafil hydrochloride)

NDA#

NDA#

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)

IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of

summary for that investigation.

YES NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES NO

If yes, explain:

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Study 12093 and Study 12094

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

- a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

- b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1
IND # 57703 YES ! NO
! Explain:

Investigation #2
IND # 57703 YES ! NO
! Explain:

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1
!
!
YES ! NO
Explain: ! Explain:

Investigation #2
!
!
YES ! NO
Explain: ! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES NO

If yes, explain:

Name of person completing form: Eufrecina DeGuia
Title: Senior Regulatory Health Project Manager
Date: 06/17/2010

Name of Office/Division Director signing form: George Benson, M.D.
Title: Division Deputy Director

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200179	ORIG-1	BAYER HEALTHCARE PHARMACEUTICA LS INC	VARDENAFIL HCL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

EUFRECINA P DEGUIA
06/17/2010

GEORGE S BENSON
06/17/2010

NDA 200179

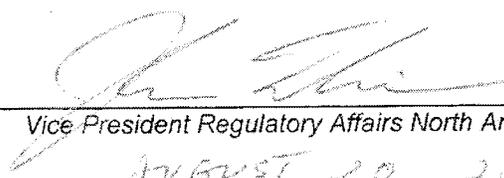
(b) (4) (vardenafil hydrochloride)

Original New Drug Application
eCTD sequence number: 0000

Module 1.3.3: Debarment Certification

Bayer hereby certifies under FD&C Act, Section 306(k)(1) that it did not and will not use in any capacity the services of any person debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Date / Signature: _____


Vice President Regulatory Affairs North America

AUGUST 20, 2007