CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-630

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

1.3.1. PATENT AND EXCLUSIVITY INFORMATION FOR VFEND® (VORICONAZOLE) POWDER FOR ORAL SUSPENSION

1.	Active Ingredient:	(2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoro-4-pyrimidinyl)-1-(1*H*-1,2,4-triazol-1-yl)-2-butanol with an empirical formula of $C_{16}H_{14}F_3N_5O$ and a molecular weight of 349.3.
2.	Strengths:	40mg voriconazole/ ml oral suspension
3.	Trade Name:	VFEND®
4.	Dosage Form/Route of Administration:	Oral
5.	Application Firm Name:	Pfizer Inc
6.	NDA Number:	NDA 21-630 Powder For Oral Suspension
7.	Exclusivity Period:	New Chemical Entity exclusivity for voriconazole runs through May 24, 2007
8.	Applicable Patent Numbers and Expiration Dates:	5,116,844 exp. August 11, 2009 5,364,938 exp. November 15, 2011 5,567,817 exp. October 22, 2013 5,773,443 exp. January 25, 2011

1.3.2. PATENT CERTIFICATION

With respect to the drug, VFEND®, which is the subject of this Application (NDA 21-630) and the U.S. patents that are listed in Module 1 Section 1.3.1 of this Application, Pfizer certifies that the drug, VFEND®, pharmaceutical compositions thereof, and methods of treating fungal infections are claimed in U.S. Patents Nos. 5,116,844; 5,364,938; 5,567,817 and 5,773,443.

EXCLUSIVITY SUMMARY for NDA # 21-630 SUPPL # N/A
Trade Name VFEND® for Oral Suspension Generic Name Voriconazole

Applicant Name Pfizer, Inc. HFD-590
Approval Date December 19, 2003

PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain 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 an original NDA? YES /_x_/ NO /___/

   b) Is it an effectiveness supplement? YES /__/ NO /___/

      If yes, what type(SE1, SE2, etc.)?

   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 /_X_/

Applicant did not argue that the application contains studies other than bioavailability/bioequivalence studies.

   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 /_x_/

      If the answer to (d) is "yes," how many years of

exclusivity did the applicant request?

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

YES /___/ NO /_x_/

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use? (Rx to OTC) Switches should be answered No - Please indicate as such).

YES /___/ NO /_x_/

If yes, NDA # _____ Drug Name

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 8.

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

YES /___/ NO /_x_/

IF THE ANSWER TO QUESTION 3 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 /_x_/ NO /___/

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

NDA # 21-266 VFEND (voriconazole) Tablets

NDA # 21-267 VFEND IV (voriconazole) for Injection

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 /___/ N/A /_x_/

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. IF "YES," GO TO PART III.

PART III: THREE-YEAR EXCLUSIVITY FOR NDA'S 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 /_X_/

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.

   For the purposes of this section, studies comparing two

products with the same ingredient(s) are considered to be bioavailability studies.

(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 /___/ N/A /___/

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:

Investigation #1, Study # _____

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 /___/

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

   NDA # _____ Study #
   NDA # _____ Study #
   NDA # _____ Study #

   (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 /___/

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

NDA # _____ Study #

NDA # _____ Study #

(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"):

Investigation #___: Study # _____

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 # _____ 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 /___/ Explain _____ NO /___/ Explain _____

_____	!	_____
Investigation #2	!	
YES /___/ Explain _____	!	NO /___/ 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: _____

_____

_____

Rebecca D. Saville
Signature of Preparer Date
Title: Regulatory Project Manager

Renata Albrecht
Signature of Office or Division Director Date

cc:
Archival NDA
HFD- /Division File
HFD- /RPM
HFD-093/Mary Ann Holovac
HFD-104/PEDS/T.Crescenzi

Form OGD-011347

Revised 8/7/95; edited 8/8/95; revised 8/25/98, edited 3/6/00

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

/s/

Renata Albrecht

12/19/03 04:16:51 PM

PEDIATRIC PAGE

(Complete for all APPROVED original applications and efficacy supplements)

NDA/BLA # : 21-630 Supplement Type (e.g. SE5): N/A Supplement Number:

Stamp Date: March 17, 2003 Action Date: January 17, 2004
Trade and generic names/dosage form: VFEND® (voriconazole) for Oral Suspension

Applicant: Pfizer, Inc. Therapeutic Class: Antifungal
Indication(s) previously approved:

Each approved indication must have pediatric studies: Completed, Deferred, and/or Waived.

Number of indications for this application(s): 3

Indication #1: Invasive aspergillosis

Is there a full waiver for this indication (check one)?

__ Yes: Please proceed to Section A.

X No: Please check all that apply: ____Partial Waiver __X__Deferred ____Completed
NOTE: More than one may apply
Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:
Products in this class for this indication have been studied/labeled for pediatric population
☐ Disease/condition does not exist in children
Too few children with disease to study
☐ There are safety concerns
Other:_

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min_____ kg_____ mo._____ yr._____ Tanner Stage_____
Max_____ kg_____ mo._____ yr._____ Tanner Stage_____

Reason(s) for partial waiver:
☐ Products in this class for this indication have been studied/labeled for pediatric population
☐ Disease/condition does not exist in children
☐ Too few children with disease to study
☐ There are safety concerns
☐ Adult studies ready for approval
☐ Formulation needed
☐ Other:_____

If studies are deferred, proceed to Section C. If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section C: Deferred Studies

Age/weight range being deferred:

2-18 years of age deferred
0-2 years of age deferred

Min _____	**kg_____**	**mo._____**	**yr._____**	**Tanner Stage_____**
Max_____	**kg_____**	**mo._____**	**yr._____**	**Tanner Stage_____**

Reason(s) for deferral:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- **X Adult studies ready for approval**
- ☐ **Formulation needed**

Other:_____

Date studies are due (mm/dd/yy): 12/31/2004

If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section D: Completed Studies

Age/weight range of completed studies:

Min _____	**kg_____**	**mo._____**	**yr._____**	**Tanner Stage_____**
Max_____	**kg_____**	**mo._____**	**yr._____**	**Tanner Stage_____**

Comments:

Attachment A

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

Indication #2: Serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium* spp., including *Fusarium solani*, in patients intolerant of or refractory to other therapy

Is there a full waiver for this indication (check one)?

- ☐ **Yes: Please proceed to Section A.**

- **X No: Please check all that apply: ____Partial Waiver __x__Deferred ____Completed**
  NOTE: More than one may apply
  Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- ☐ **Other:_____**

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min ____ kg____ mo.____ yr.____ Tanner Stage_____
Max____ kg____ mo.____ yr.____ Tanner Stage_____

Reason(s) for partial waiver:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- ☐ **Adult studies ready for approval**
- ☐ **Formulation needed**
- ☐ **Other:_____**

If studies are deferred, proceed to Section C. If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section C: Deferred Studies

Age/weight range being deferred:

2-18 years of age deferred
0-2 years of age deferred

Min _____ kg_____ mo._____ yr._____ Tanner Stage_____
Max_____ kg_____ mo._____ yr._____ Tanner Stage_____

Reason(s) for deferral:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- **X Adult studies ready for approval**
- ☐ **Formulation needed**
- ☐ **Other:_____**

Date studies are due (mm/dd/yy): 12/31/2004

If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section D: Completed Studies

Age/weight range of completed studies:

Min _____ kg_____ mo._____ yr._____ Tanner Stage_____
Max_____ kg_____ mo._____ yr._____ Tanner Stage_____

Comments:

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.

Indication #3: Esophageal Candidiasis

Is there a full waiver for this indication (check one)?

- ☐ **Yes: Please proceed to Section A.**

X No: Please check all that apply: ____Partial Waiver _X_Deferred ____Completed
NOTE: More than one may apply
Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- ☐ **Other:**_____

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min _____ **kg**_____ **mo.**_____ **yr.**_____ **Tanner Stage**_____
Max_____ **kg**_____ **mo.**_____ **yr.**_____ **Tanner Stage**_____

Reason(s) for partial waiver:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- ☐ **Adult studies ready for approval**
- ☐ **Formulation needed**
- ☐ **Other:**_____

If studies are deferred, proceed to Section C. If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section C: Deferred Studies

Age/weight range being deferred:

2-18 years of age deferred
0-2 years of age deferred

Min _____ **kg**_____ **mo.**_____ **yr.**_____ **Tanner Stage**_____
Max_____ **kg**_____ **mo.**_____ **yr.**_____ **Tanner Stage**_____

Reason(s) for deferral:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- X **Adult studies ready for approval**
- ☐ **Formulation needed**
- ☐ **Other:**_____

Date studies are due (mm/dd/yy): 12/31/2004

If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section D: Completed Studies

Age/weight range of completed studies:

Min ____	**kg____**	**mo.____**	**yr.____**	**Tanner Stage____**
Max____	**kg____**	**mo.____**	**yr.____**	**Tanner Stage____**

Comments:

This page was completed by:

{See appended electronic signature page}

Rebecca Saville, Pharm.D., M.S.
Regulatory Project Manager

cc: NDA
HFD-960/ Terrie Crescenzi
(revised 1-18-02)

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT, PEDIATRIC TEAM, HFD-960
301-594-7337

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/s/

Rebecca Saville
12/8/03 12:33:50 PM
Voriconazole POS Pediatric Page

NDA 21-630

VFEND® (voriconazole) Powder for Oral Suspension

DEBARMENT CERTIFICATION
[FD&C Act 306(k)(1)]

Pfizer hereby certifies 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.

Shawn W. Garvey — March 3, 2003

Signature of Company Representative — Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0297
Expiration Date: February 29, 2004.

USER FEE COVER SHEET

See Instructions on Reverse Side Before Completing This Form

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. See exceptions on the reverse side. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment instructions and fee rates can be found on CDER's website: http://www.fda.gov/cder/pdufa/default.htm

1. APPLICANT'S NAME AND ADDRESS

Pfizer Global Research & Development
50 Pequot Avenue
New London, CT 06320

2. TELEPHONE NUMBER *(Include Area Code)*

(212) 733-5688

3. PRODUCT NAME

VFEND (voriconazole) ®

4. BLA SUBMISSION TRACKING NUMBER (STN) / NDA NUMBER

N021630

5. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL?

☐ YES ☒ NO

IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

IF RESPONSE IS 'YES', CHECK THE APPROPRIATE RESPONSE BELOW:

☐ THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION.

☐ THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO:

_____
(APPLICATION NO. CONTAINING THE DATA).

6. USER FEE I.D. NUMBER

4508

7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92
(Self Explanatory)

☐ A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE
(See item 7, reverse side before checking box.)

☐ THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act
(See item 7, reverse side before checking box.)

☐ THE APPLICATION IS A PEDIATRIC SUPPLEMENT THAT QUALIFIES FOR THE EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food, Drug, and Cosmetic Act
(See item 7, reverse side before checking box.)

☐ THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY
(Self Explanatory)

8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?

☐ YES ☒ NO

(See Item 8, reverse side if answered YES)

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

and

Food and Drug Administration
CDER, HFD-94
12420 Parklawn Drive, Room 3046
Rockville, MD 20852

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SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
Rita A Wittich	Rita Wittich Vice President, Worldwide Regulatory Strategy	03/12/03

FORM FDA 3397 (3/01)

Created by: PSC Media Arts (301) 443-2454 EF

MEMORANDUM OF TELECON

DATE: December 12, 2003

APPLICATION NUMBER: NDA 21-630, VFEND (voriconazole) for Oral Suspension

BETWEEN:

Name: Maureen Garvey, Ph.D., Director, Regulatory Strategy
Phone: (212) 733-5688
Representing: Pfizer, Inc.

AND

Name: Renata Albrecht, M.D., Division Director
Marc Cavaille-Coll, M.D., Ph.D., Medical Officer
Sary Beidas, M.D., Medical Reviewer
Philip Colangelo, Pharm.D., Ph.D., Clin. Pharm. & Biopharmaceutics Team Leader
Gerlie De Los Reyes, Ph.D., Clinical Pharmacology & Biopharmaceutics Reviewer
Ellen F. Molinaro, R.Ph., Chief, Project Management Staff
Rebecca Saville, Pharm.D., Regulatory Project Manager
Division of Special Pathogen and Immunologic Drug Products, HFD-590

SUBJECT: Labeling Negotiations

Background:

On December 5, 2003, FDA communicated to Pfizer changes to the March 14, 2003 proposed package insert labeling via email. On December 12, 2003, Maureen Garvey and Rebecca Saville reached agreement on minor changes in the package insert via telephone, prior to this teleconference.

Discussion/Agreements:

An agreement was reached on the final label for VFEND for Oral Suspension and the following changes will be made in the final draft of the labeling:

- Pfizer will remove "because this may alter voriconazole bioavailability from the oral suspension" in the Incompatibilities section, and will replace "voriconazole" with "VFEND" in the Use in Adults section of D&A.

- A new label had been approved in the time period since the submission of the proposed labeling for the oral suspension, incorporating the indication for the treatment of esophageal candidiasis. It was agreed that Pfizer would prepare a new version of the

labeling incorporating all approved changes as well as the oral suspension dosing directions for patients with esophageal candidiasis in the D&A section of the label.

In addition, the Division requested that Pfizer commit to conducting a two-way drug interaction study with voriconazole and oral contraceptives.

Rebecca D. Saville, Pharm.D.
Regulatory Project Manager

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

/s/

Rebecca Saville
12/22/03 02:27:40 PM
CSO
NDA 21-630

WorldWide Regulatory Affairs
Pfizer Inc
50 Pequot Avenue
New London, CT 06320

Global Research & Development

19 December 2003

Renata Albrecht, M.D., Director
Division of Special Pathogens and Immunologic
Drug Products HFD #590
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
ATT: DOCUMENT CONTROL ROOM
9201 Corporate Boulevard
Rockville, MD 20850

Dear Dr. Albrecht:

Re: NDA-21-630 - VFEND® (voriconazole) for Oral Suspension

General Correspondence-Final Labeling

We refer to the 14 March 2003 initial filing of NDA 21-630 for the new formulation, VFEND (voriconazole) for Oral Suspension. We refer also to the FDA-revised label for VFEND for Oral Suspension, received 05 December 2003, and the following subsequent correspondences:

- 12 December 2003 FDA-Pfizer labeling negotiation teleconference to discuss the 05 December 2003 FDA-revised label. At this teleconference, agreement was reached on the final label for VFEND for Oral Suspension. An updated US Package Insert (USPI) had been approved in the time period since the submission of the proposed USPI for VFEND for Oral Suspension, incorporating, in particular, the indication for the treatment of esophageal candidiasis and drug interaction information. Therefore, it was agreed that Pfizer would prepare a new version of the USPI, incorporating all approved changes. In addition, at this teleconference, FDA requested that Pfizer commit to conduct a voriconazole/oral contraceptive, two-way drug interaction study.
- 15 December 2003 Pfizer email to FDA identifying previously submitted information regarding the potential for drug interaction between voriconazole and oral contraceptives
- 16 December 2003 teleconference to discuss FDA request for voriconazole/oral contraceptive drug interaction study. At this teleconference, Pfizer agreed to conduct the requested study.
- 17 December 2003 teleconference to discuss final revisions to the DOSAGE AND ADMINISTRATION text, being made for increased clarity.

- 18 December 2003 teleconference to discuss deletion (from USPI versions being submitted at this time) of drug interaction information which was submitted as Changes Being Effected Supplements on October 21 and November 12, 2003, and which is included in the current USPI although still under review at FDA.

As discussed, this submission consists of Pfizer's commitment to conduct the drug interaction study and the final agreed Package Insert.

We commit to conduct a voriconazole/oral contraceptive two-way interaction study according to the following timeline:

Date of protocol submission:	15 March 2004
Date of study start:	15 April 2004
Date of final report submission:	15 March 2005

The final agreed Package Insert includes all revisions discussed on December 12, 17 and 18, as indicated in the attached strikeout version of the USPI. The enclosed CD contains the following versions of the final agreed Package Insert:

- Strikeout/underline Word version of approved Package Insert, with revisions shown by strikeout and underline, including revisions regarding efavirenz and ritonavir drug interaction studies.
- "Clean" Word version of final agreed Package Insert
- PDF version of final agreed Package Insert with Pfizer pedigree

This electronic submission is approximately 1.19 MB in size. The CD-ROM has been scanned with McAfee VirusScan Version 4.5.1 SP1 and is virus free.

This correspondence is being sent to you via email and as official electronic copy. If you have any questions regarding this correspondence, please call me at (212) 733-5688. We look forward to the completion of this review. Please include this information in our files for NDA 21-630.

Thank you very much.

Sincerely,

Maureen H. Garvey

Maureen H. Garvey, Ph.D.
Director
Worldwide Regulatory Strategy
Worldwide Regulatory Affairs

Enclosures

cc: Rebecca Saville Pharm.D., Project Manager
Submission No. 0007

MEMORANDUM OF TELECON

DATE: December 18, 2003

APPLICATION NUMBER: NDA 21-630, VFEND (voriconazole) for Oral Suspension

BETWEEN:

Name: Maureen Garvey, Ph.D., Director, Regulatory Strategy
Phone: (212) 733-5688
Representing: Pfizer, Inc.

AND

Name: Ellen F. Molinaro, R.Ph., Chief, Project Management Staff
Rebecca Saville, Pharm.D., Regulatory Project Manager
Division of Special Pathogen and Immunologic Drug Products, HFD-590

SUBJECT: Requests for corrections to the Package Insert

Background:
Following the December 17, 2003 teleconference about the Dosage and Administration section of the package insert, Pfizer sent a draft of the package insert for the oral suspension via e-mail. Dr. Garvey requested that Dr. Saville verify that the agreements made in the December 17, 2003 teleconference had been incorporated correctly prior to mailing the archivable submission. During verification, it was discovered that this draft (and the draft submitted December 16, 2003) included information regarding drug interactions with ritonavir and efavirenz. These changes had been submitted as "Changes Being Effected" supplemental new drug applications on October 21, 2003 and November 12, 2003 and are currently being reviewed by the Division.

Discussion:
DSPIDP advised Pfizer that FDA cannot approve a package insert that contains information that has not been reviewed yet. Therefore, Pfizer would need to remove this information from the draft labeling submitted for the approval of the oral suspension. We explained that Changes Being Effected (CBEs) absolutely could be included when Pfizer prepares the Final Printed Labeling in response to this approval letter; this is in accordance with the regulations. However, FDA could not include a package insert containing the new information with the approval letter until we had actually completed our review.

In addition, Pfizer was asked to remove "VFEND tablet" from the statement "Patients who weigh 40 kg or more should receive an oral maintenance dose of 200 mg VFEND tablet every 12 hours" found in the footnote of the table in the Dosage and Administration section of the package insert

Agreements:

resubmit draft labeling for the oral suspension.

Pfizer agreed to change the statement to "Patients who weigh 40 kg or more should receive an oral maintenance dose of 200 mg every 12 hours."

Ellen F. Molinaro, R.Ph.
Chief, Project Management Staff

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/s/

Rebecca Saville
12/19/03 06:13:40 PM
CSO
NDA 21-630

Ellen Molinaro
12/19/03 06:16:22 PM
CSO
NDA 21-630

MEMORANDUM OF TELECON

DATE: December 17, 2003

APPLICATION NUMBER: NDA 21-630, VFEND® (voriconazole) for Oral Suspension

BETWEEN:

Name: Maureen Garvey, Ph.D., Director, Regulatory Strategy
Alice Baruch, M.D., Clinical Pharmacologist
Representing: Pfizer, Inc.

AND

Name: Renata Albrecht, M.D., Division Director
Marc Cavaille-Coll, M.D., Ph.D., Medical Team Leader
Ellen Molinaro, R.Ph., Chief, Project Management Staff
Rebecca Saville, Pharm.D., Regulatory Project Manager
Division of Special Pathogen and Immunologic Drug Products, HFD-590

SUBJECT: Labeling: Dosage and Administration Section of Package Insert

Background:
Pfizer submitted final draft labeling of the package insert for the oral suspension on December 16, 2003. Upon review, the Division became concerned about the clarity of the Dosage and Administration section due to the addition of liquid volumes in parentheses throughout the text and the absence of any distinction that these volumes pertained to the oral suspension rather than the intravenous dosage form.

Discussion:
The Division advised Pfizer that, although factually correct, the inclusion of liquid volumes in parentheses after each reference to a dose in the Dosage and Administration section of the label could lead to two types of potential errors.

(a) Health-care providers may be led to believe that the oral suspension is the only appropriate oral dosage form to provide the dose.
(b) Health-care providers may believe the volume refers to the intravenous dosage form.

We reminded Pfizer that many package inserts for products available as multiple dosage forms do not include the liquid volume after each reference to a dose; Diflucan is an example. The Division noted that, health care providers, when given bioequivalence information, are generally proficient at converting between dosage forms to administer a specific dose to the patient. Because the tablets and oral suspension can be dosed the same and the IV must be dosed differently, providers only need to know the dose for each route of administration. We suggested that throughout the text, "maintenance dose" should be preceded by either "oral" or "intravenous" and that the volumes and "tablets" should be removed. The Division agreed that Pfizer should also remove the subsections (tablet and suspension) of the oral maintenance dose in the table and to state "200 mg every 12 hours." The Division informed Pfizer that a conversion

table for the tablet and oral suspension could be added if Pfizer chose to include one, but the Division would let Pfizer make that decision.

Pfizer was asked to clarify the directions for dosing in the paragraph regarding coadministration with phenytoin.

Agreements:

- Pfizer agreed to adjust the table and to eliminate the volumes from the text.
- Pfizer agreed to specify "the intravenous maintenance dose" and "the oral maintenance dose" in the paragraph regarding coadministration with phenytoin.

Rebecca Saville, Pharm.D., Regulatory Project Manager, DSPIDP
Ellen Molinaro, R.Ph., Chief, Project Management Staff, DSPIDP

Renata Albrecht, M.D.
Division Director, DSPIDP

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/s/

Rebecca Saville
12/19/03 04:01:05 PM
CSO
Dosage and Administration Labeling Changes

Renata Albrecht
12/19/03 04:18:34 PM
MEDICAL OFFICER

Ellen Molinaro
12/19/03 05:09:18 PM
CSO

MEMORANDUM

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

DATE: December 12, 2003

BETWEEN: Maureen Garvey, Ph.D.

AND: Rebecca Saville, Pharm.D.

SUBJECT: **Labeling Negotiations**
NDA 21-630, VFEND (voriconazole) for Oral Suspension

Background:
On December 5, 2003, FDA communicated to Pfizer changes to the March 14, 2003 proposed package insert labeling via email.

Discussion and Agreements:

Pfizer will replace VFEND with voriconazole prior to "is designated chemically..." and "drug substance is a ..."; Pfizer will delete the second VFEND in the title and reduce the font size of the "for Oral Suspension" on pg 1.

Pfizer will change the acronym BID dosing to q12h (Clinical Pharmacology - Absorption section) to be consistent with the rest of the document.

Pfizer will add information in the Gender section of Pharmacokinetics in Special Populations, and will add the word "oral" prior to the word "suspension" in this information.

Pfizer will delete the 0.0 from the volumes and capitalize "L" in mL in the D&A section.

Pfizer will change "Once reconstituted, VFEND Oral Suspension should only be administered using the oral syringe supplied with each pack to "The reconstituted oral suspension should only be administered using the oral dispenser supplied with each pack" in the Instructions for Use section of D&A to reduce confusion with IV directions and to be consistent with their other labeling.

Rebecca D. Saville, Pharm.D., M.S.
Regulatory Project Manager
DSPIDP

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/s/

Rebecca Saville
12/19/03 07:35:02 PM
CSO
NDA 21-630

NDA REGULATORY FILING REVIEW
(Including Memo of Filing Meeting)

NDA # 21-630
Trade Name: VFEND® .
Generic Name: Voriconazole
Strengths: 40mg/ml after reconstitution

Applicant: Pfizer, Inc.

Date of Application: March 14, 2003
Date of Receipt: March 17, 2003
Date clock started after UN: N/A
Date of Filing Meeting: May 5, 2003
Filing Date: May 16, 2003

Action Goal Date (optional): December 19, 2003 User Fee Goal Date: January 17, 2004

Indication(s) requested:
(1) Invasive aspergillosis
(2) Serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium* spp., including *Fusarium solani*, in patients intolerant of or refractory to other therapy

Type of Original NDA: (b)(1) ___X___ (b)(2) _____
OR
Type of Supplement: (b)(1) _____ (b)(2) _____
NOTE: A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). If the application is a (b)(2) application, complete the (b)(2) section at the end of this review.

Therapeutic Classification: S ___X_____ P _____
Resubmission after withdrawal? ___No_____ Resubmission after refuse to file? ___No_____
Chemical Classification: (1,2,3 etc.) ___3____
Other (orphan, OTC, etc.) ___No____

User Fee Status: Paid ___X_____ Exempt (orphan, government) _____
Waived (e.g., small business, public health) _____

Form 3397 (User Fee Cover Sheet) submitted: **YES** NO
User Fee ID # ___4508_____
Clinical data? No Referenced to NDA #

Is there any 5-year or 3-year exclusivity on this active moiety in either a (b)(1) or a (b)(2) application?
YES NO
If yes, explain:
New molecular entity, exclusivity given for VFEND Tablets (NDA 21-266) and IV (NDA 21-267) approved May 24,2002.

Does another drug have orphan drug exclusivity for the same indication? YES **NO**

If yes, is the drug considered to be the same drug according to the orphan drug definition of sameness [21 CFR 316.3(b)(13)]? [N/A] YES NO

Is the application affected by the Application Integrity Policy (AIP)? YES [NO]

If yes, explain.

If yes, has OC/DMPQ been notified of the submission? [N/A] YES NO

- Does the submission contain an accurate comprehensive index? [YES] NO
- Was form 356h included with an authorized signature? [YES] NO
  If foreign applicant, both the applicant and the U.S. agent must sign.
- Submission complete as required under 21 CFR 314.50? [YES] NO
  If no, explain:
- If an electronic NDA, does it follow the Guidance? N/A [YES] NO
  If an electronic NDA, all certifications must be in paper and require a signature.
  Which parts of the application were submitted in electronic format?
  All parts were submitted electronically, except the certifications which required signatures.

Additional comments:

- If in Common Technical Document format, does it follow the guidance? [N/A] YES NO
- Is it an electronic CTD? [N/A] YES NO
  If an electronic CTD, all certifications must be in paper and require a signature.
  Which parts of the application were submitted in electronic format?
  All parts were submitted electronically, except the hardcopy certifications which required signatures.
- Patent information submitted on form FDA 3542a? [YES] NO
- Exclusivity requested? YES, _____years [NO]
  Note: An applicant can receive exclusivity without requesting it; therefore, requesting exclusivity is not required.
- Correctly worded Debarment Certification included with authorized signature? [YES] NO
  If foreign applicant, both the applicant and the U.S. Agent must sign the certification.

  NOTE: Debarment Certification should use wording in FD&C Act section 306(k)(1) i.e., *"[Name of applicant] hereby certifies 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."* Applicant may not use wording such as "To the best of my knowledge . . . ."

- Financial Disclosure forms included with authorized signature? [YES] NO
  (Forms 3454 and 3455 must be used and must be signed by the APPLICANT.)
- Field Copy Certification (that it is a true copy of the CMC technical section)? [YES] NO

Refer to 21 CFR 314.101(d) for Filing Requirements

- PDUFA and Action Goal dates correct in COMIS? [YES] NO
  If not, have the document room staff correct them immediately. These are the dates EES uses for calculating inspection dates.

- Drug name/Applicant name correct in COMIS? [YES] NO
  (If not, have the Document Room make the corrections).

- List referenced IND numbers: 66,410

- End-of-Phase 2 Meeting(s)? Date(s) _____ [NO]
  If yes, distribute minutes before filing meeting.

- Pre-NDA Meeting(s)? Date(s) _____ [NO]
  If yes, distribute minutes before filing meeting.

Project Management

- All labeling (PI, PPI, MedGuide, carton and immediate container labels) consulted to DDMAC? [YES] NO

- Trade name (plus PI and all labels and labeling) consulted to ODS/DMETS? YES [NO]

- MedGuide and/or PPI (plus PI) consulted to ODS/DSRCS? [N/A] YES NO

- If a drug with abuse potential, was an Abuse Liability Assessment, including a proposal for scheduling, submitted? [N/A] YES NO

If Rx-to-OTC Switch application:

- OTC label comprehension studies, all OTC labeling, and current approved PI consulted to ODS/DSRCS? [N/A] YES NO

- Has DOTCDP been notified of the OTC switch application? [N/A] YES NO

Clinical:

- If a controlled substance, has a consult been sent to the Controlled Substance Staff? [N/A] YES NO

Chemistry

- Did applicant request categorical exclusion for environmental assessment? [YES] NO
  If no, did applicant submit a complete environmental assessment? YES NO
  If EA submitted, consulted to Nancy Sager (HFD-357)? YES NO

- Establishment Evaluation Request (EER) submitted to DMPQ? [YES] NO

- If a parenteral product, consulted to Microbiology Team (HFD-805)? [N/A] YES NO

If 505(b)(2) application, complete the following section: N/A

- Name of listed drug(s) and NDA/ANDA #:

- Describe the change from the listed drug(s) provided for in this (b)(2) application (for example, "This application provides for a new indication, otitis media" or "This application provides for a change in dosage form, from capsules to solution").

- Is the application for a duplicate of a listed drug and eligible for approval under section 505(j) as an ANDA? (Normally, FDA will refuse-to-file such NDAs.)

  YES NO

- Is the extent to which the active ingredient(s) is absorbed or otherwise made available to the site of action less than that of the reference listed drug (RLD)? (See 314.54(b)(1)). If yes, the application should be refused for filing under 314.101(d)(9).

  YES NO

- Is the rate at which the product's active ingredient(s) is absorbed or otherwise made available to the site of action unintentionally less than that of the RLD? (See 314.54(b)(2)). If yes, the application should be refused for filing under 314.101(d)(9).

  YES NO

- Which of the following patent certifications does the application contain? Note that a patent certification must contain an authorized signature.

  ____ 21 CFR 314.50(i)(1)(i)(A)(1): The patent information has not been submitted to FDA.

  ____ 21 CFR 314.50(i)(1)(i)(A)(2): The patent has expired.

  ____ 21 CFR 314.50(i)(1)(i)(A)(3): The date on which the patent will expire.

  ____ 21 CFR 314.50(i)(1)(i)(A)(4): The patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted.

  IF FILED, and if the applicant made a "Paragraph IV" certification [21 CFR 314.50(i)(1)(i)(A)(4)], the applicant must submit a signed certification that the patent holder was notified the NDA was filed [21 CFR 314.52(b)]. Subsequently, the applicant must submit documentation that the patent holder(s) received the notification ([21 CFR 314.52(e)].

  ____ 21 CFR 314.50(i)(1)(ii): No relevant patents.

  ____ 21 CFR 314.50(i)(1)(iii): The patent on the listed drug is a method of use patent and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent. Applicant must provide a statement that the method of use patent does not claim any of the proposed indications.

  ____ 21 CFR 314.50(i)(3): Statement that applicant has a licensing agreement with the patent owner (must also submit certification under 21 CFR 314.50(i)(1)(i)(A)(4) above.)
  ____ Written statement from patent owner that it consents to an immediate effective date upon approval of the application.

- Did the applicant:

  - Identify which parts of the application rely on information the applicant does not own or to which the applicant does not have a right of reference?

    YES NO

  - Submit a statement as to whether the listed drug(s) identified has received a period of marketing exclusivity?

    YES NO

  - Submit a bioavailability/bioequivalence (BA/BE) study comparing the proposed product to the listed drug?

    N/A YES NO

  - Certify that it is seeking approval only for a new indication and not for the indications approved for the listed drug if the listed drug has patent protection for the approved indications and the applicant is requesting only the new indication (21 CFR 314.54(a)(1)(iv).?

    N/A YES NO

- If the (b)(2) applicant is requesting exclusivity, did the applicant submit the following information required by 21 CFR 314.50(j)(4):

  - Certification that each of the investigations included meets the definition of "new clinical investigation" as set forth at 314.108(a).

    YES NO

  - A list of all published studies or publicly available reports that are relevant to the conditions for which the applicant is seeking approval.

    YES NO

  - EITHER
    The number of the applicant's IND under which the studies essential to approval were conducted.

    IND # _____ NO

    OR

    A certification that it provided substantial support of the clinical investigation(s) essential to approval if it was not the sponsor of the IND under which those clinical studies were conducted?

    N/A YES NO

- Has the Director, Div. of Regulatory Policy II, HFD-007, been notified of the existence of the (b)(2) application?

  YES NO

ATTACHMENT

MEMO OF FILING MEETING

DATE: May 5, 2003

BACKGROUND:
VFEND® Tablets and I.V. for infusion has been already approved for the treatment of invasive aspergillosis and infections caused by *Scedosporium spp.* and F*usarium spp.* This NDA is submitted in support of a new formuation, VFEND (voriconazole) for oral suspension.

ATTENDEES:
Sary Beidas, M.D., Medical reviewer
Cheryl Dixon, Ph.D., Statistical reviewer
Gene Holbert, Ph.D., Chemistry reviewer
Shukal Bala, Ph.D., Microbiology Team Leader
Marc Cavaille Coll, M.D., Ph.D., Medical Team Leader
Philip Colangelo, Pharm.D., Ph.D., Clinical Pharmacology and Biopharmaceutics Team Leader
Ellen Frank, R.Ph., Chief, Project Management Staff
Kalavati Suvarna, Ph.D., Microbiology Reviewer
Gerlie De Los Reyes, Ph.D., Clinical Pharmacology and Biopharmaceutics Reviewer
Andrei Nabakowoski, Pharm.D., Regulatory Project Manager
Jouhayna Saliba, Pharm.D., Regulatory Project Manager

ASSIGNED REVIEWERS:

Discipline	**Reviewer**
Medical:	Sary Beidas, M.D.
Secondary Medical:	Marc Cavaille-Col, M.D., Ph.D.
Statistical:	Cheryl Dixon, Ph.D.
Pharmacology:	Owen McMaster, Ph.D.
Statistical Pharmacology:	N/A
Chemistry:	Gene Holbert, Ph.D.
Environmental Assessment (if needed):	N/A
Biopharmaceutical:	Gerlie De Los Reyes, Ph.D.
Microbiology, sterility:	N/A
Microbiology, clinical (for antimicrobial products only):	Suvarna Kalavati
DSI:	N/A
Regulatory Project Management:	Rebecca Saville, Pharm.D.
Other Consults:	Iris Masucci, DDMAC

Per reviewers, are all parts in English or English translation? **YES** NO
If no, explain:

CLINICAL FILE ___X___ REFUSE TO FILE _____

- Clinical site inspection needed: YES **NO**

- Advisory Committee Meeting needed? YES, date if known _____ **NO**

- If the application is affected by the AIP, has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance? **N/A** YES NO

CLINICAL MICROBIOLOGY FILE __X__ REFUSE TO FILE _____

STATISTICS FILE __X__ REFUSE TO FILE _____

BIOPHARMACEUTICS FILE __X__ REFUSE TO FILE _____

- Biopharm. inspection needed: YES **NO**

PHARMACOLOGY FILE __X__ REFUSE TO FILE _____

- GLP inspection needed: YES **NO**

CHEMISTRY FILE __X__ REFUSE TO FILE _____

- Establishment(s) ready for inspection? **YES** NO
- Microbiology YES NO

ELECTRONIC SUBMISSION:
Any comments:

REGULATORY CONCLUSIONS/DEFICIENCIES:

_____ The application is unsuitable for filing. Explain why:

__X__ The application, on its face, appears to be well organized and indexed. The application appears to be suitable for filing.

_____ No filing issues have been identified.

__X__ Filing issues to be communicated by Day 74.
Conveyed via teleconference on May 6, 2003.List (optional): ??

ACTION ITEMS:

1. If RTF, notify everybody who already received a consult request of the RTF action. Cancel the EER.

2. If filed and the application is under the AIP, prepare a letter either granting (for signature by Center Director) or denying (for signature by ODE Director) an exception for review.

3. Document filing issues/no filing issues conveyed to applicant by Day 74.

Rebecca D. Saville
Regulatory Project Manager, HFD-590

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/s/

Rebecca Saville
12/16/03 12:40:13 PM
CSO
VFEND POS NDA Regulatory Filing Review

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILING REVIEW LETTER

NDA 21-630

Pfizer Inc.
Attention: Marueen Garvey, Ph.D.
Director, Worldwide Regulatory Affairs
50 Pequot Avenue
New London, CT 06320

Dear Dr. Garvey:

Please refer to your March 14, 2003 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VFEND® (voriconazole) powder for oral suspension, 40mg/ml.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application has been filed under section 505(b) of the Act on May 16, 2003 in accordance with 21 CFR 314.101(a).

At this time, we have not identified any potential filing 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.

If you have any questions, call Jouhayna Saliba, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Diana Willard
6/20/03 11:30:52 AM
For Ellen Frank, R.Ph.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: April 3, 2003

To: Maureen Garvey	**From:** Jouhayna Saliba
Company: Pfizer	Division of Special Pathogens and Immunologic Drug Products
Fax number: 212-573-7314	**Fax number:** 301-827-2475
Phone number: 212-733-5688	**Phone number:** 301-827-2387

Subject: CMC comments

Total no. of pages including cover: 3

Comments:

Document to be mailed: ☐ YES ☑ NO

DATE: April 3, 2003

TO: Maureen Garvey, Ph.D.
Regulatory Affairs

ADDRESS: Pfizer Inc.
Eastern Point Road
Groton, CT 06340

FROM: Jouhayna Saliba, Pharm.D.
Regulatory Project Manager

NDA: 21-630 VFEND® (voriconazole) for Oral Suspension

SUBJECT: CMC comments

We refer to your new drug application (NDA) submitted March 14, 2003. Please confirm the following with regard to your manufacturing facilities.

- ALL manufacturing and testing facilities are listed in the attachment to form 356h
- There are NO other facilities
- The roles/responsibilities for each site listed are complete and correct, and
- The facilities will be ready for inspection as of the date listed (19-MAY-2003).

If you have any questions please contact Jouhayna Saliba, Project Manager at 301-827-2387.

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/s/

Jouhayna Saliba
4/3/03 02:21:28 PM
CSO

DIVISION OF SPECIAL PATHOGENS & IMMUNOLOGIC DRUG PRODUCTS

Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-590
Rockville, MD 20850

FACSIMILE TRANSMISSION COVER SHEET

Date: 3/28/03 **Number of Pages (including cover sheet):** 4

To: Maureen Garvey

Company: Pfizer, Inc

Fax Number: 212-573-7314

Message: NDA 21-630 Acknowledgement Letter

From: Susan Peacock (for Joumana Saliba)

Title: Regulatory Project Manager

Telephone: 301-827-2173 **Fax Number:** 301-827-2475

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-630

Pfizer Global Research & Development
Attention: Maureen H. Garvey, Ph.D., Director
Regulatory Strategy, Policy and Registration, Worldwide Regulatory Affairs
50 Pequot Ave
New London, CT 06320

Dear Dr. Garvey:

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

Name of Drug Product: VFEND ® (voriconazole) Powder for Oral Suspension

Review Priority Classification: Standard (S)

Date of Application: March 14, 2003

Date of Receipt: March 17, 2003

Our Reference Number: NDA 21-630

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 May 16, 2003, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be January 16, 2004.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products, HFD-590
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products, HFD-590
Attention: Document Room N-115
9201 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions, call Jouhayna Saliba, Pharm.D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
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/s/

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