

Memorandum of Teleconference

DATE OF MEETING: November 16, 1998

IND: _____

DRUG: Voriconazole

INDICATION: Triazole anti-fungal agent

SPONSOR: Pfizer, Inc.

TYPE OF MEETING: Teleconference to Discuss Ophthalmologic Adverse Events

FDA Attendees, Titles, and Offices:

Marc Cavallé-Coll, M.D., Ph.D., Clinical Team Leader
Wiley Chambers, M.D., Division of Anti-inflammatory, Analgesic and Ophthalmologic Drug Products
Rigoberto Roca, M.D., Medical Officer
Rosemary Tiernan, M.D., Medical Officer
Laurie Bernato, R.N., MN, Project Manager

Pfizer Attendees, Titles, and Offices:

Maureen H. Garvey, Ph.D., Director, Regulatory Affairs Department
Michael Leeming, Ph.D., Clinical Research
Konrad Tomaszewski, Ph.D., Clinical Safety
Robert Swanson, Ph.D., Clinical Research

Background:

The Pfizer Position Paper on Voriconazole and Altered Vision was contained in the May 8, 1998 and July 28, 1998 submissions. Pfizer requested FDA concurrence with their plan to address visual disturbances. FDA responded via a telefacsimile on October 9, 1998 that included our consultation with a CDER ophthalmologist. Pfizer responded via a submission dated November 4, 1998 that included a request for a teleconference to clarify the FDA comments.

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November 16, 1998

Objective:

To discuss and clarify the FDA ophthalmologic comments sent to Pfizer on October 9, 1998.

Discussion:

The numbered items were conveyed in the October 9, 1998 facsimile. The discussion follows in *Italics*.

1. Ocular testing performed to date has had numerous problems.

Dr. Chambers stated that he needed more information concerning the tests with abnormal baselines or tests that they were unable to complete or fixate. The ERG results in Study 150-231 had patients with scores significantly different than baseline.

Action/Follow-Up Items: Pfizer will utilize an outside consultant to assist with the interpretation of the ocular testing results and retina development.

2. The utility of animal histology is questionable.

Dr. Tomaszewski reported that there was no long-term structural damage observed in the study participants. However, Dr. Chambers felt that there may be a physiological effect and that additional histology is needed. Dr. Chambers stated that the residual photophobia whereby the pupil does not respond properly may be due to infection or increased sensitivity. Therefore, he recommended more electrophysiological testing in patients.

Action/Follow-Up Items: Pfizer agreed to conduct more physiological testing.

3. Patients treated for >28 days should have additional testing.

Dr. Chambers stated that since these changes occur slowly, there is a need to look at long-term testing of color vision and visual fields. Dr. Tomaszewski noted that this population of patients is very ill and that it is difficult to evaluate them. Dr. Chambers advised Pfizer to test normal volunteers including follow-up after completion of treatment.

Action/Follow-Up Items: Pfizer will do long term testing on patients even after they have finished treatment. They will evaluate patients comparing their baseline after treatment was completed to their status at the time of reevaluation. Normal volunteers will be included in the study.

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4. The retina is still developing in children up to nine years of age.

The Pfizer attendees informed us that they had utilized an outside consultant who advised them that the retina was developed between the ages of 2-4 years. Dr. Chambers stated that the retina might be completely developed by ages 7-9.

Action/Follow-Up Items: Pfizer agreed to do further investigation via another consultation to verify the age of the complete development of the retina

5. It is not possible to conclude that the visual cortex is not affected.

Dr. Tomaszewski stated that there was no effect on the cortex by voriconazole. Dr. Chambers noted that the ERG's reviewed did not present a classic picture. The effect may be coming from the retina and these changes may not be reversible.

Action/Follow-Up Items: Pfizer will provide the FDA with individual ERG results on additional patients.

6. Irreversible ERG changes cannot be ruled out.

Pfizer agreed to use normal volunteers to collect more data since it is difficult to test the target population because they are very ill. The FDA recommended additional patients examined over an increased amount of time.

Action/Follow-Up Items: Pfizer agreed to study more patients on a long-term basis.

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November 16, 1998

Concurrence:
HFD-590/TL/Cavaillé-Coll/
HFD-550/MO/Chambers/
HFD-590/MO/Teirnan/
HFD-590/PM/Bernato/drafter/010599

Distribution:
HFD-590/TL/Cavaillé-Coll
HFD-550/MO/Chambers
HFD-590/MO/Teirnan
HFD-590/Division File
HFD-590/PM/Bernato
IND _____
IND _____

To DFS faxed to sponsor without this page / 199

MEMORANDUM OF TELEPHONE FACSIMILE CORRESPONDENCE

DATE: 10 March 1998

TO: Maureen Garvey
Regulatory Affairs

ADDRESS: Pfizer
235 East 42nd Street
New York, NY 10017-5755
(212) 733-5688
(212) 573-7314 (fax)

FROM: Ellen C. Frank, R.Ph.

THROUGH: Marc Cavallé-Coll, M.D., Ph.D., Clinical Team Leader

IND: _____

SUBJECT: Teleconference scheduled for Friday, March 13, 1998, 11:30 a.m. EST
Submission 063/046: Protocol 150-608

Please refer to your submission dated February 4, 1998, containing protocol 150-608 entitled, "A Randomized, Comparative, Multicenter Study of Voriconazole versus Conventional Amphotericin B in the Treatment of Candidemia in Non Neutropenic Subjects." Please also refer to our telephone conversation of March 4, 1998, scheduling a teleconference to provide comments on this protocol. The following comments and requests are provided in advance of the teleconference.

BIOPHARMACEUTICS/CLINICAL PHARMACOLOGY

These comments may apply to Phase III Studies other than 150-608. If responses to these comments have been provided previously, it is acceptable to either provide a copy of the previous response or indicate the previous submission number. Please note that the Clinical Pharmacology and Biopharmaceutics Review Officer will not be present for Friday's teleconference. Responses to these comments may be provided in writing or by communicating the previous submission number to me via telephone.

1. Please indicate the rationale for the voriconazole dose reduction in subjects that weigh less than 40 kg.

2. Please indicate how the timing of drug administration relative to meals was determined. Will a food effect study be performed with the final tablet formulation?
3. The effect of voriconazole on rifabutin pharmacokinetics should be considered. Other CYP3A4 inhibitors have been shown to increase rifabutin concentrations.
4. The potential for drug interactions with protease inhibitors other than ritonavir should be considered. The approved labeling for the other protease inhibitors indicate the types of interactions that have been observed between the protease inhibitors and other CYP3A4 inhibitors and substrates.

CLINICAL

The description of Voriconazole dose reduction (Section 9.2.1 Study Treatments: Study Drug Administration/Voriconazole arm) appears to address patients who are unable to tolerate 4 mg/kg q 12 h, or 300 mg bid orally. These doses, however, are those to which patients can be increased under the guidelines for dose escalation. Please clarify whether this represents a typographical error, and if not, please indicate the guidelines for dose reduction in a patients that are unable to tolerate the standard study doses, (intravenous, 3 mg/kg q 12 h, or oral, 200 mg bid).

STATISTICAL

The Sample Size Determination (Appendix G) states that the goal of the analysis is to demonstrate that the rate of response to antifungal therapy in subjects randomized to voriconazole is no more than 20% lower than the rate of response in subjects randomized to treatment with conventional amphotericin B. We believe that a statement of "no more than 20% lower" contained in the description of this clinical study in a potential label for voriconazole would be misleading; the reader may infer that equivalence has been demonstrated when, in fact, it has not. Therefore, we recommend that an equivalence trial design be utilized.

The following FDA personnel are scheduled to participate in the teleconference.

Marc Cavaillé-Coll, M.D., Ph.D., Clinical Team Leader
Rigoberto Roca, M.D., Medical Officer
Aloka Chakravarty, Ph.D., Acting Statistical Team Leader
Cheryl Dixon, Ph.D., Statistical Reviewer
Robin Anderson, R.N., Senior Regulatory Management Officer

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

ES

Ellen C. Frank, R.Ph.
Regulatory Management Officer
Division of Special Pathogen and Immunologic Drug Products

March 9, 1998

Concurrence:

HFD-590/TL/Cavaillé-Coll/031098
HFD-590/MO/Roca/031098
HFD-590/ActingStatTL/Chakravarty/031098
HFD-590/Stat/Dixon/031098
HFD-590/ActBiopharmTL/Funmi/signed review/030698
HFD-590/Biopharm/Reynolds/031098
HFD-590/RMO/Frank/drafter/031098

Distribution:

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**MEMORANDUM OF TELEPHONE FACSIMILE CORRESPONDENCE**

DATE: 22 December 1997

TO: Maureen Garvey
Regulatory Affairs

ADDRESS: Pfizer
235 East 42nd Street
New York, NY 10017-5755
(212) 733-5688
(212) 573-7314 (fax)

FROM: Ellen C. Frank, R.Ph.

THROUGH: Teresa Wu, M.D.

IND: _____

SUBJECT: Teleconference scheduled for Tuesday, December 23, 1997, 11:00 a.m. EST
Submission 058: Protocol 150-603

Please refer to your submission dated November 11, 1997, containing protocol 150-603 entitled, "A Randomized, Open-Label Comparative, Multicenter Trial of Voriconazole vs. AmBisome for Empirical Antifungal Therapy in Immunocompromised Patients with Persistent Fever and Neutropenia." Please also refer to our telephone conversation of December 17, 1997, scheduling a teleconference to provide clinical and statistical comments on this protocol. The following comments and requests are provided in advance of the teleconference.

1. Please indicate the role of the Mycosis Study Group (MSG) in this trial. Please also indicate whether the participating site for this trial will be the same as that for the AmBisome trial. This information will assist us in predicting if the accrual rate, incidence of fungal infections and patient management will be comparable between these two trials which have a very similar trial design.
2. Because this trial is not blinded, we are concerned that investigators' management might be influenced by their knowledge of patients' treatment assignments. We recommend that you propose a separate end-point team to conduct an independent assessment of the results. We would be glad to review and comment on your proposal.
3. We recommend that a minimum of two temperature measurements of $>38^{\circ}\text{C}$, greater than three hours apart, be required at entry.

4. Please specify, under Exclusion Criteria, which category(ies) of fungal infections are considered "documented" deeply invasive fungal infections. Please incorporate the following comment into your consideration.
5. Please be aware that the categorization of fungal infection as described in Appendix H is a function of investigators' diagnostic intensity which is expected to have a wide range of variation. Since a "possible" diagnosis carries the lowest level of diagnostic confidence, we recommend that this category be excluded in the efficacy analysis.
6. We recommend that a quantitative definition of urinary tract infection be provided in the protocol. According to the AmBisome trial, a criterion of >10 CFU/ml was used.
7. We would like you to be aware of the following potential caveats of the empirical trial:
 - A. As described in the protocol, drugs that may interfere with Voriconazole are prohibited during study, yet drugs that are known to enhance the potential for AmBisome-induced renal toxicity are allowed. We understand that this provision is for practical reasons. However, this differential treatment with respect to the respective "anticipated" toxicity profiles for the two study drugs underscores a potential bias in favor of voriconazole.
 - B. The composite endpoint, which is used to determine the rate of overall response, encompasses both efficacy and safety assessments of study drugs. If the results of the comparison between two treatments with respect to the efficacy and safety assessments, when analyzed separately, show opposite directions, the conclusion of an equivalence based on the rate of overall response may be highly problematic.
 - C. It is difficult to anticipate the incidence of breakthrough fungal infection for each treatment group in this empirical trial. If the incidence rate for the AmBisome arm is lower than that observed in the AmBisome trial (3.2%), to claim that two treatments are equivalent in the context of a very low incidence of breakthrough fungal infection may also be problematic.

The following FDA personnel are scheduled to participate in the teleconference.

Marianne Mann, M.D., Acting Clinical Team Leader
Teresa Wu, M.D., Medical Officer
Aloka Chakravarty, Ph.D., Acting Statistical Team Leader
Cheryl Dixon, Ph.D., Statistical Reviewer
Ellen Frank, R.Ph., Regulatory Management Officer

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

 / S /
Ellen C. Frank, R.Ph.
Regulatory Management Officer
Division of Special Pathogen and Immunologic Drug Products

Concurrence:

HFD-590/ActingTL/Mann/... /S/ -
HFD-590/MO/Wu/122297 (electronically)
HFD-590/ActingStatTL/Chakravarty/^{no response}/122297
HFD-590/Stat/Dixon/^{no response = concurrence}/122297
HFD-590/RMO/Frank/drafter/122297

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Record of Teleconference D1V

IND: _____

Date: August 16, 1996

Drug: Voriconazole Oral and Intravenous

Sponsor: Pfizer Inc.

BETWEEN: Representatives of PfizerMartha Brumfield, Senior Associate Director of Regulatory Affairs
C. Leigh Holmes, Senior Executive Director of Drug Safety Evaluation
Guy Paulus, Senior Vice President of Safety EvaluationAND: Representatives of DAVDPJames Farrelly, Pharmacology Team Leader
Owen McMaster, Pharmacology Reviewer
Vikki Kinsey, Consumer Safety Officer

Subject: CAC final report

Background: This teleconference was initiated by the FDA to relay comments to the sponsor resulting from the August 6, 1996 CAC Executive Committee meeting. The FDA submitted two carcinogenicity protocols to the CAQ committee to obtain feedback on the use of voriconazole in rats and mice (See attached memorandum).

Discussion Points:

1. Mice studies: It was agreed by both parties that the doses of voriconazole that will be used in mice studies will be 10 mg/kg, 30 mg/kg, and 100 mg/kg/day.
2. Rat studies: Dr. Farrelly stated that both methods of administration (oral gavage and in diet administration) were acceptable. He added that the advantages of oral gavage administration are that the animals will receive improved exposure to the drug and that the incidence of liver necrosis might be expected to be less. The sponsor chose the in diet method of administration.
3. The sponsor was informed that a copy of the Executive CAC final report will be sent to them.

The teleconference was cordial throughout.

Attachment/Handouts:

Memorandum: CAC Executive Committee Final Report

concurrency:

CSO/drafter: Kinsey

HFD-530/TL (Pharm)/Farrell *S/9/12/96*

HFD-530/Pharm/McMaster *9/13/96*

cc: Original IND. _____
Division file
HFD-530/MO/Wut
HFD-530/CSO/Kinsey
HFD-530/Pharm/McMaster

Address: c:\wpfiles\tc48735.3

14 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.



Division of Special Pathogen and Immunologic Drug Products

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

FACSIMILE TRANSMISSION

DATE: March 11, 1999 Number of Pages (including cover sheet): 4
TO: Maureen Garvey
COMPANY: Pfizer, Inc.
(212) 733-5688
FAX NUMBER: (212) 573-7314
MESSAGE: February 3, 1999,- Meeting Minutes- Discussion of Chemistry,
Manufacturing and Control Program For IND's

NOTE: We are providing the attached information via telefacsimile for your convenience. Please feel free to contact me if you have any questions regarding the contents of this transmission.

FROM: Laurie Bernato
TITLE: Project Manager

TELEPHONE: (301) 827-2127

FAX NUMBER:(301) 827-2475

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CHEMISTRY COMMENTS

1. **Synthesis, Starting Materials and Proposed Control Strategy-** The quality of the starting materials will be closely monitored and a control strategy where the routes of synthesis will be known. Are our proposals acceptable to the FDA?

The proposals are acceptable.

2. **Strategy for qualification of commercial manufacturing sites for drug substance and drug product-** Pfizer presented their proposed strategy for qualification of commercial manufacturing sites. Is this plan acceptable to the FDA?

The FDA is in agreement with your plans.

3. **Strategy for particle size and endotoxin testing-** Pfizer asked for Agency input as to the acceptability of their specification and control strategy for particle size and endotoxin testing.

This proposal is acceptable.

4. **Strategy and rationale for the proposed choice of dissolution methods-** Pfizer proposed a Q value of — at 45 minutes utilizing USP apparatus 2 at 50 rpm in water.

The Biopharmaceutical reviewers said that they preferred a Q value of — in forty-five minutes using — HCL.

5. **Rationale for enantiomeric control-** To be controlled at the drug substance stage.

This rationale is acceptable to the FDA

6. **Bracketing approach for stability program to support bottle count/bottle size options-**

This approach is acceptable.

7. **Overall approach to testing and controls for the lyophile for intravenous injection-** Pfizer presented their proposals to tests and controls to ensure drug specifications.

This was also acceptable. Dr. Schmuff indicated that we would be following the lead of the Neuropharmacology Division with respect to sulfobutylether beta-cyclodextrin.



Central Research Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Clinical & Scientific Affairs

F A X C O V E R S H E E T

DATE: July 26, 1999 **TIME:** 2:30 PM
TO: Matthew Baccho **PHONE:**
Food and Drug Admin. **FAX:** 301-827-2475
FROM: Maureen H. Garvey **PHONE:** 212-773-5688
Pfizer Inc **FAX:** 212 573 5431 (Bldg 219-6)

RE: Overheads for Voriconazole July 7, 1999 Pfizer/FDA Meeting
CC:

Number of pages including cover sheet: 12

Message

Dear Matt,

Attached are the overheads used at the July 7, 1999 Pfizer/FDA Meeting for your informal use as we discussed. They will be officially submitted to the Vori INDs within the next few days.

Maureen H. Garvey

cc: Cynthia Thompson for Maureen Garvey

Voriconazole Safety Update

- **Updated Visual disturbances strategy**
 - New information
 - Proposals for obtaining additional information
 - Impact on programme
 - Proposed analyses in NDA
- **Hepatic issues**
 - Overview
 - Proposed analyses in NDA

Visual Disturbances - historical perspective

- **Altered perception of light, blurred vision, photophobia**
- **Incidence around 20%**
- **Transient:**
 - onset around 30 minutes after oral dose
 - duration around 30 minutes
- **Retina proposed site of action**
 - ERG decrease in b-wave

Monitoring strategy

- **Phase I**
 - Funduscopy, visual fields, acuity
- **Study 673 - extensive testing**
- **All phase III (except 150-305)**
 - Funduscopy
 - Bedside acuity and visual fields
- **Study 150-305 - more extensive testing**
 - To be discussed

New information

- **Study 150-305**
 - Blinded data on visual function tests
- **Study 150-673**
 - Comparative data on visual function tests
- **Preclinical data**
 - Dog ERG study
 - Morphometric analysis of eye

150-305 results

- Double-blind comparative study of voriconazole versus fluconazole in oesophageal candidiasis
- Total of 390 subjects
- >50% received > 2 weeks treatment
- Study still blind - group X vs group Y presentation
- Visual tests performed at B/L, EOT and EOS
 - Visual acuity, colour vision, funduscopy, contrast sensitivity

Results

- No discernible differences between groups X and Y in function testing
 - Fluconazole not associated with visual disturbances
- No discernible differences between groups X and Y in structure
 - determined by fundus examination

Study 150-673

- **Comparative dose escalation study**
 - 200 mg voriconazole, bid; 7 subjects
 - 300 mg voriconazole, bid; 9 subjects
 - 400 mg fluconazole, od; 6 subjects
- **Treatment period 14 days**
- **Extensive testing at B/L and EOT:**
 - Visual acuity, colour vision, contrast sensitivity, photostress recovery time, visual fields, intra-ocular pressure, slit-lamp examinations, funduscopy

Study 150-673 results

- **Preliminary results available**
 - No formal comparisons
- **Examination of data from each group suggest no differences**
- **No effect on visual function could be detected**

Dog ERG results

- Intravenous infusion (3 doses) to anaesthetised dog:
 - 4.5, 9.5, 16 mcg/ml
- ERG measured after blue flash
- Results:
 - Dose-related decrease in a-wave amplitude
 - Dose-related decrease in a-wave implicit time
 - Decrease in b-wave amplitude at 2 high doses

Toxicology update

- Additional morphometric analysis of eye
 - 1- and 6-month dogs
 - 6-month rats
- Morphometry measures retinal thickness
 - Number of nuclei in inner and outer layers
- No differences between treated and control animals in retinal thickness

Proposals for generating more information on visual function

- **Extra information to address:**
 - **Cumulative effect on visual function**
 - **Visual function in elderly**
 - **Reversibility of effect on ERG**
 - **Visual function in patients in long-term studies**
 - **Paediatric development of voriconazole**

MD Electrophysiology study

- **Study effect on ERG (primary endpoint) after multiple doses (30 days)**
- **Will address reversibility and cumulative effect on visual function**
 - **Satisfactory results will enable paediatric studies**
- **Will include other functional testing**
- **Seen as pivotal study to address FDA concerns**

MD ERG Study - issues

- Study is logistically difficult
- Ideal is one centre
 - Same equipment used throughout study
 - Same technical staff
 - Same conditions at each visit
- Proving problematic to find centre

MD ERG Study - issues

- Design of study limits number of volunteers that can be recruited
 - At most 4 subjects can be included
 - 43 days from B/L to EOS
- Study may not complete until 2001
 - Data not available in NDA
 - Delay to paediatric development if results needed

Impact of MD ERG study on paediatric programme

- 3 available options to initiate paediatric program:
 1. Wait for full results of ERG study
 - Paediatric programme delayed
 2. Perform interim analysis of ERG study
 - Compromises “pivotal” study; under powered decision
 3. Initiate paediatric programme on current data
 - Low number of subjects limits risk
- Sponsor favours option 3
proposes ↗ delinking MD ERG from paediatric program

Testing in patients

- Already being tested
 - Bedside acuity and fields; funduscopy
- Problem with obtaining interpretable data in these subjects
 - Sick population (immune compromised)
 - Problematic intercurrent illness
 - Large number of concomitant medications
 - Baseline unlikely

Proposal for generating data in patients

- **Perform prospective visual safety study**
 - Population needing long term treatment (e.g. coccidioides and paracoccidioides)
 - Able to perform baseline testing
 - Visual acuity, colour vision, visual fields, funduscopy by standard methodology
- **Study would generate visual data after several months treatment**

Testing in ongoing studies

- **Use comparative studies only to aid interpretation**
- **Propose amendment for more testing**
 - Studies 307/603 only
 - High recruiting centres with ophthalmology dept.
 - Baseline to be taken up to 30 days after start of study
- **Testing to include**
 - Corrected distance visual acuity, slit lamp examination, funduscopy, colour vision, automated visual fields

Proposed Analysis for NDA

- **Will include mostly phase I data**
 - Times of onset and duration most often accurately recorded
 - PK comparison possible
- **Data from phase II/III will be examined by other factors that are specific to patients**
 - eg underlying condition, disease under study

Summary

- **New clinical data indicate no difference in function vs fluconazole**
- **Additional data (available only after 1st submission)**
 - MD ERG study
 - Patients from Aspergillosis studies 307/602
 - Prospective long term patient study
- **Sponsor believes this programme will address FDA concerns**

Hepatic issues

- Elevated LFTs expected with azole antifungals
- Also seen with amphotericin B formulations
- Voriconazole incidence (150-304):
 - AST > 3X ULN: 9%
 - ALT > 3X ULN: 18%
 - TB > 1.5X ULN: 21%
 - ALP > 3X ULN: 18%
- Conservative criteria for clinical significance?

Proposed definition of clinically significant LFTs

- Given by Walsh et al. (1999) NEJM 340:764
 - ALT/AST > 5 X BL if BL < 2X ULN
 - ALT/AST > 3 X BL if BL 2-5 X ULN
 - ALT/AST > 2 X BL if BL 5-10 X ULN
- Applied to voriconazole programme:
 - Voriconazole: ALT - 7% AST - 7%
 - Comparator: ALT - 9% AST - 6%

Proposed analyses for ISS

- Use similar definition for clinically significant to Walsh et al.
- Incidence of significant abnormalities to be analysed by
 - Demographics
 - Disease under study
 - Co-morbidities
 - Onset and reversibility
 - Dose



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

FACSIMILE TRANSMITTAL SHEET

DATE: May 10, 2002

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: Pharmacokinetic data obtained from adolescents

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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DIVISION OF SPECIAL PATHOGENS & IMMUNOLOGIC DRUG PRODUCTS

Center for Drug Evaluation and Research
Food and Drug Administration
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Rockville, MD 20850

FACSIMILE TRANSMISSION COVER SHEET

Date: 5/3/02 Number of Pages (including cover sheet): 3

To: Muneem Garvey

Company: pfizer

Fax Number: 202-573-7314

Message: _____

From: J. Saliba

Title: _____

Telephone: 301-827-2387 Fax Number: _____

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DIVISION OF SPECIAL PATHOGENS & IMMUNOLOGIC DRUG PRODUCTS

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Food and Drug Administration
9201 Corporate Boulevard, HFD-590
Rockville, MD 20850

FACSIMILE TRANSMISSION COVER SHEET

Date: 3/28/02 Number of Pages (including cover sheet): 3

To: Mameen Ganiou

Company: efje

Fax Number: 202-573-7314

Message: Extension of pediatric deferral date.

From: Jahayra Salah

Title: Project manager

Telephone: 202-827-2387 Fax Number: 202-827-2475

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

FACSIMILE TRANSMITTAL SHEET

DATE: March 13, 2002

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: Preparation for our teleconference on 3/14/02	

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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

FACSIMILE TRANSMITTAL SHEET

DATE: January 16, 2002

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: Comment regarding QTc Study	

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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MODE = MEMORY TRANSMISSION

START=NOV-16 12:58

END=NOV-16 12:59

FILE NO. = 095

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001	OK	*	912125737314	003/003	00:00'47"

-FOOD & DRUG ADMIN. -

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- ***** -

301 827 2474- *****

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: 11/16/01 Number of Pages (including cover sheet): 3

To: maureen Garvey

Company: Pfizer

Fax Number: 212-573-7314

Message: Extension letter

From: Jouhanna Salha

Title: _____

Telephone: 301-827-2387 Fax Number: 301-827-2475

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MODE = MEMORY TRANSMISSION

START=DEC-21 15:35

END=DEC-21 15:37

FILE NO. =037

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	#	912125737314	007/007	00:02:09

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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: 12/21/01 Number of Pages (including cover sheet): 7

To: Mameen Garvey

Company: Pfizer

Fax Number: 212-573-7314

Message: please confirm receipt of letter

From: J. O'Hayna Saliba

Title: Project Manager

Telephone: 301-827-2387 Fax Number: 301-827-2435

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

FACSIMILE TRANSMITTAL SHEET

DATE: October 17, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: Requests for information	

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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

FACSIMILE TRANSMITTAL SHEET

DATE: October 16, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: Protocol 150-606 Division's comments to Pfizer

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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Food and Drug Administration
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Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: August 24, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: FDA recommendations to AC briefing document	

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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

FACSIMILE TRANSMITTAL SHEET

DATE: July 25, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: Requests for information	

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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Food and Drug Administration
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FACSIMILE TRANSMITTAL SHEET

DATE: July 13, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen 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: Protocol A1501010- Division's comments to Pfizer	

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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Food and Drug Administration
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Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: June 15, 2001

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: In Vitro Dissolution Testing	

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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FACSIMILE TRANSMITTAL SHEET

DATE: June 12, 2001

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: In Vitro Dissolution Testing	

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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Food and Drug Administration
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Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: May 22, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Special Pathogen and Immunologic Drug Products
Fax number: 212-573-7314	Fax number: [REDACTED]
Phone number: 212-733-5688	Phone number: 301-827-2387
Subject: Request prior to our meeting 5/25	

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: May 11, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Division of Special Pathogen and Immunologic Drug Products
Fax number: 212-573-7314	Fax number: [REDACTED]
Phone number: 212-733-5688	Phone number: 301-827-2387
Subject: Requests for new datasets	

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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

FACSIMILE TRANSMISSION COVER SHEET

Date: 4/16/01 Number of Pages (including cover sheet): 7

To: Maureen Gurney

Company: Pfizer

Fax Number: 212-573-7314

Message: minutes from Feb 5th telecon

573
7314

From: Jouhayna Saliba

Title: Project manager

Telephone: 301-827-2127 Fax Number: 301-827-2475

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Food and Drug Administration
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Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: January 9, 2001

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Division of Special Pathogen and Immunologic Drug Products
Fax number: 212-573-7314	Fax number: [REDACTED]
Phone number: 212-733-5688	Phone number: 301-827-2423
Subject: PK information	

Total no. of pages including cover: 2

Comments:

Document to be mailed: YES NO

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Center for Drug Evaluation and Research
Office of Drug Evaluation IV

FACSIMILE TRANSMITTAL SHEET

DATE: November 20, 2000

To: Maureen Garvey	From: Jouhayna Saliba
Company: Pfizer	Division of Division of Special Pathogen and Immunologic Drug Products
Fax number: [REDACTED]	Fax number: 301-827-2475
Phone number: [REDACTED]	Phone number: 301-827-2423
Subject: Minutes of Teleconference Nov. 3, 2000	

Total no. of pages including cover: 4

Comments:

Document to be mailed: YES NO

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

FACSIMILE TRANSMISSION COVER SHEET

Date: 11/20/00 Number of Pages (including cover sheet): 4

To: Maureen Gawrey, Regulatory Affairs

Company: Pfizer

Fax Number: 212-573-5431

Message: I have faxed the minutes from our
teleconference on November 3, 2000. If you have
any questions please contact me at 301-827-2423.
thanks

From: Jahayra Saliba

Title: projed Manager

Telephone: 301-827-2423 Fax Number: 301-827-2475

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MODE = MEMORY TRANSMISSION

START=NOV-02 16:56

END=NOV-02 16:57

FILE NO. = 182

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-FOOD & DRUG ADMIN. -

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- ***** - 301 827 2474- *****

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

FACSIMILE TRANSMISSION COVER SHEET

Date: Nov. 2, 2000 Number of Pages (including cover sheet): 2

To: Maureen Garvey, Reg. Affairs

Company: Pfizer

Fax Number: (212) 573-7314

Message: _____

From: Jouhanna Saliba

Title: Project Manager

Telephone: 301-827-2423 Fax Number: 301-827-2475

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MODE = MEMORY TRANSMISSION

START=NOV-02 17:35

END=NOV-02 17:36

FILE NO. = 186

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001	OK	*	912125737314	002/002	00:00'43"

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***** - ** - 301 827 2474- *****

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

FACSIMILE TRANSMISSION COVER SHEET

Date: 11/2/2000 Number of Pages (including cover sheet): 2

To: Mawaan Barve, Ph.D.

Company: Pfizer, Inc.

Fax Number: (212) 573-7314

Message: _____

From: Les Chan.

Title: Regulatory Project Manager

Telephone: (301) 827-2155 Fax Number: (301) 827-2475

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US Mail address:
FDA/CDER/HFD-590
5600 Fishers Lane
Rockville, MD 20857

Overnite Delivery:
9201 Corporate Blvd.
Rockville, MD 20850

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Transmitted to FAX Number: 212-573-5431 (Bldg. 219-6)
Attention: Maureen Garvey, Ph.D.
Company Name: Pfizer Central Research
Telephone: 212-733-5688
Subject: teleconference minutes
Date: 7/25/00
No. of pages (including cover sheet): 6
From: Diana M. Willard
Phone: 301-827-2127
Fax: 301-827-2475

Signature 

Please note that it is the sponsor's responsibility to bring to the attention of the Division any perceived differences in meeting outcomes.



Central Research Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Clinical & Scientific Affairs

F A X C O V E R S H E E T

ATTN: Leo Chan - Please Deliver ASAP

DATE: October 18, 1999 **TIME:** 10:37 AM
TO: Leo Chan, R.Ph **PHONE:** 301-827-2155
Food and Drug Admin. **FAX:** 301-827-2326
FROM: Maureen H. Garvey **PHONE:** 212-773-5688
Pfizer Inc **FAX:** 212 573 5431 (Bldg 219-6)

RE: Minutes of the March 10, 1999 FDA meeting

CC:

Number of pages including cover sheet: 8

Message

Leo,

Attached, as I promised, are the Pfizer Minutes of the March 10, 1999 meeting with FDA, redacted to omit several internal comments and the distribution list.

These minutes, together with the overheads shown at the meeting, will be submitted to the voriconazole INDs.

Please call Cynthia Thompson at 212-573-2570 to confirm receipt of this fax. I will be calling you to discuss alternate dates for the meeting to discuss the clinical pharmacology of voriconazole and the pediatric program. Unfortunately one of our key participants is not available on December 1.

Cynthia Thompson for Maureen H. Garvey



Central Research Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Clinical & Scientific Affairs

F A X C O V E R S H E E T

DATE: March 4, 1999 **TIME:** 2:45 PM
TO: Ms. Laurie Bernato RN **PHONE:** 301-827-2387
Food and Drug Admin. **FAX:** 301-827-2475
FROM: Maureen H. Garvey **PHONE:** 212-773-5688
Pfizer Inc **FAX:** 212 573 5431 (Bldg 219-6)

RE: Voriconazole IND — (IV) and IND — (oral)
Minutes of 8/15/97 teleconference

CC:

Number of pages including cover sheet: 6

Message

Laurie,

Attached are the Pfizer minutes from the 8/15/97 teleconference. These will be submitted to the Voriconazole INDs as you suggested.

Maureen H. Garvey