DIVISION OF CARDIO-RENAL DRUG PRODUCTS
FOOD AND DRUG ADMINISTRATION

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Transmitted to FAX Number:	212-857-3558
Attention:	**Mr. John Picciano**
Company Name:	Pfizer
Phone:	212-573-1975
Subject:	4/3/01 Telecon Minutes
Date:	4/17/01
Pages including this sheet:	3

From:	**Zelda McDonald**
Phone:	**301-594-5333**
Fax:	**301-594-5494**

You are responsible for notifying us of any significant differences in understanding you may have regarding the meeting outcomes (as reflected in the minutes).

PLEASE LET ME KNOW YOU RECEIVED THIS. THANKS!

cc:
Orig.
HFD-110
HFD-110/McDonald/Matthews

01P-0010

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Minutes of Telecon Meeting
Pfizer- ALLHAT Advisory Committee

Date of Meeting: April 3, 2001

NDA Number: 19-668

Meeting Chair: Raymond Lipicky, M.D.

Meeting Participants:

FDA, HFD-110

Raymond Lipicky, M.D.	Director, Div. of Cardio-Renal Drug Products, HFD-110
Colleen LoCicero, R.Ph.	Regulatory Health Project Manager, HFD-110
Daryl Allis, M.S.N., F.N.P.	Regulatory Health Project Manager, HFD-110

Pfizer

Michael Sweeney, M.D.	Director/Teamleader, WWT Viagra/Cardura
Sharon Mallen, M.D.	Medical Director, Medical Administration
Suzanne LoGalbo	Director/Teamleader, Regulatory Affairs
John Picciano	Director, Drug Regulatory Affairs

Background

National Heart, Lung, and Blood Institute is in the process of conducting a clinical trial (IND) entitled the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). An initial publication based on interim analysis of the ALLHAT trial has been published comparing chlorthalidone and doxazosin. Based on ALLHAT, a citizen petition has been filed requesting that the FDA take certain actions regarding Pfizer's doxazosin including scheduling a meeting of the Cardio-Renal Advisory Committee. Pfizer requested this telecon to discuss their presentation for the Advisory Committee meeting scheduled for May 24, 2001. Pfizer expressed a copy of their slide presentation to Dr. Lipicky.

Meeting

Following a quick review of the slide presentation, there were two points discussed.

1. The first objective, ' should be revised. Dr. Lipicky suggested removing the ' language from this statement in order to avoid the issue of is any "antihypertensive safe and effective."

2. Dr. Lipicky needs to evaluate the benefit of including data from the Systolic Hypertension in the Elderly Program (SHEP) study in this presentation. The sponsor pointed out that SHEP would demonstrate that doxazosin has a neutral effect on CHF, compared to the known beneficial effect of diuretics in treating CHF. Therefore, you would expect to see an increase in heart failure in patients not treated with a diuretic.

Dr. Lipicky explained that each group (NHLBI, Citizen Petition, and Pfizer) would have 20 minutes for their presentation and should expect numerous questions and lengthy discussions. Therefore, they should keep

the planned presentation and accompanying slides to a minimum, but be prepared to address any anticipated questions and have back-up slides available.

Dr. Lipicky asked if Pfizer would be submitting a document. Pfizer stated they would have a briefing document that does not need redaction out by April 20, 2001. The sponsor asked when the Advisory Committee materials and the Citizen Petitioners' materials with attachments would be released to the public and whether all materials would be released at the same time. Dr. Lipicky stated that all the Advisory Committee documents would be released at the same time. In addition, Dr. Lipicky noted that Pfizer stated already that the Citizen Petition attachments were releasable and believed the Citizen Petition was on the web. He was not sure if the attachments were included with the petition. He told the sponsor we would check and let them know.

Conclusion
Pfizer will revise the presentation and call the Division in 1-2 weeks to discuss the changes and identify further recommendations at that time.

Addendum
After the meeting, the Division verified that the Citizen Petition with the attachments was on the web site. The sponsor was notified by telephone and given the web site address.

Meeting Recorder: **_____Daryl Allis_____**

Concurrence, Chair: _____

cc:
HFD-110/Mathews
Hirsch, HFD-580
Shames, HFD-580
Colangelo, HFD-580
Draft: 4/5/01
LoCicero: 4/9/01
Morgenstern: 4/12/01
Final: 4/13/01

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

/s/

Zelda McDonald
4/17/01 01:09:39 PM
CSO
Dr. Lipicky signed these minutes on 4/13/01

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CENTERWATCH
THOMSON HEALTHCARE

August 27, 2001

Dr. Teresa Toygo
Dockets Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Room. 1061
Rockville, MD 20857.

Dear Dr. Toygo:

I am writing to share my thoughts with the FDA on the **Draft Guidance Document for Industry – Information Program on Clinical Trials for Serious or Life Threatening Diseases: Implementation Plan, Docket # 00D1033.** It is my hope that these comments and suggestions will be considered and, if appropriate, incorporated into the final version of the Guidance Document.

As summarized in the Draft Guidance document, the Section 113 legislation requires pharmaceutical companies to list their clinical trials for serious and life-threatening illnesses with the public Internet registry established by the National Library of Medicine (NLM). The legislation calls for the National Institutes of Health to work with internal and outside agencies to establish a coordinated system of databanks for public access to government- and industry-sponsored clinical trial information. Specifically: *"The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information."*

To this end, whereas some sponsor companies may choose to list their trials directly on the public registry, the NLM has stated in writing that an intermediary -- such as CenterWatch -- can assist pharmaceutical and biotechnology companies in complying with the FDAMA 1997 mandate Section 113. CenterWatch is already in the process of working collaboratively with the NLM and its contractor, Aspen Systems, to post CenterWatch trial listings on the NLM's coordinated public clinical trials registry.

I would like to suggest that the Guidance Document, in Section B of the Implementation Plan, mention CenterWatch as an intermediary that can assist sponsor companies in complying with the FDAMA 1997 Section 113 mandate.

As background, CenterWatch is an independent publishing company focusing on the clinical trial industry, and a subsidiary of Medical Economics (publishers of the Physician's Desk Reference® and US Pharmacopoeia®). For seven years, CenterWatch has maintained one of the largest registries of clinical trials on the Internet. At the present time, more than 8,000 US-based industry-sponsored trials are listed on our web service – a large percentage of these trials target serious and life-threatening illnesses. The information that we gather from sponsor companies is IRB–approved and conforms to the parameters recommended in the Section 113 mandate including the

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study titles and summaries, eligibility requirements, trial start dates, trial locations and investigative site contact information.

CenterWatch has established a wide network of relationships and has built the necessary infrastructure to professionally maintain and support industry's involvement in complying with this mandate. Presently, more than 200 pharmaceutical and biotechnology companies list their trials routinely on the CenterWatch web service. An estimated 500 companies have used our service during the past several years. The CenterWatch listing service has received recognition from both commercial and government agencies as an independent and reputable information source. Since 1997, the NIH has been referring its patient visitors to the CenterWatch web site.

I have personally played an active role in helping to address Section 113 of the FDAMA mandate. In 1997 and 1998, I served on the NCI Steering Committee to design the initial elements of a national registry. I have participated in several meetings with the NIH during the past four years where I have shared information about the CenterWatch databank operation. During the past 18 months, I have met with Aspen Systems on several occasions to explore ways of coordinating our various databanks.

Information presented on our Clinical Trials Listing Service is managed closely and carefully by CenterWatch. We update the information on our web service several times each day. For example, if a Serious Adverse Event is reported to the IRB, CenterWatch can remove that trial listing immediately. Through our affiliates and links -- CenterWatch is already reaching as many as 8 million potential study subjects each year.

Given a well-established process, CenterWatch offers sponsor companies a relatively cost-free approach to listing their trials on *ClinicalTrials.gov*. And CenterWatch also offers a streamlined approach for the NLM to integrate various databanks. I would appreciate your consideration in designating CenterWatch as an intermediary that can assist sponsor companies in complying with the FDAMA 1997 Section 113 mandate. Within the Guidance Document Section B of the Implementation Plan, if appropriate, I would be happy to provide more information about how the submission process might work with CenterWatch involved.

Thank you for your time. Please feel free to call me at 617-856-5940 or email me at kenneth.getz@centerwatch.com with any questions.

Sincerely,

Kenneth A. Getz
President and CEO
CenterWatch, Inc.

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