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:	Minutes of 3/16/01 Telecon
Date:	3/20/01
Pages including this sheet:	3

From: **Zelda McDonald**
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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:
HFD-110/Matthews
BFriedman

01P-CC10

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Teleconference Minutes

Telecon Date: March 16, 2001
Date Requested: March 14, 2001
NDA: 19-668
Sponsor: Pfizer

Telecon Chair: Raymond Lipicky, M.D.
Telecon Recorder: Zelda McDonald
External Participant Lead: John Picciano

FDA:
Raymond Lipicky, M.D. — Director, Div. of Cardio-Renal Drug Products, HFD-110
Douglas Throckmorton, M.D. — Deputy Director, HFD-110
Zelda McDonald — RHPM, HFD-110

Pfizer
Suzanne LoGalbo, J.D. — Director, Team leader, Regulatory Affairs, Drug Regulatory Affairs
John Picciano — Director, Drug Regulatory Affairs

Background:
A clinical trial entitled the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) is being conducted at the National Heart, Lung, and Blood Institute (NHLBI). The results of an interim analysis of the ALLHAT trial have been published comparing chlorthalidone and doxazosin. Based on ALLHAT, a Citizen's 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. A telecon was held with Pfizer on February 28, 2001 wherein Dr. Lipicky invited Pfizer to make a presentation as part of the Advisory Committee meeting scheduled for May 24, 2001. Pfizer said they would get back to Dr. Lipicky as to whether they would commit to making a presentation. In a March 9, 2001 telecon, Pfizer indicated that they would be happy to make a presentation, but at that time they were only prepared to discuss, in general, what they would present. Pfizer requested this telecon to discuss the draft outline of what they planned to present (slides attached).

Telecon:
Dr. Lipicky stated that, in general, the draft looked fine. He recommended that Pfizer not discuss the SHEP or trials because that would be a discussion of whether controlling blood pressure is beneficial which is not pertinent to the issue at hand. He believed they should concentrate on the Medical Therapy of Prostate Symptoms (MTOPS) study and available morbidity/mortality data with doxazosin even if short term, i.e., what is known from controlled trials outside of ALLHAT. Dr. Throckmorton noted that it is possible SHEP and could come up, so Pfizer should be prepared with backup slides. Pfizer can mention spontaneous adverse events, but should not spend a lot of time on them.

Dr. Lipicky said he has not talked with the Dr. Cutler (NIH) or the Citizen's Petition group as to what they plan to present, so the focus may change. His expectation is that the Citizen's Petition group will say that they saw the NIH report in the published article, and they think it is important for the FDA to do something. The NIH will discuss the reason for stopping that arm of the study and why they think it is important. Pfizer should concentrate on discussion how doxazosin was evaluated in controlled trials and MTOPS and what was seen.

Agenda

- Introduction
- Doxazosin Data Review
  - Clinical Trials
    - general overview
    - review of Pfizer clinical trials
    - review of selected cardiovascular events
    - CHF study
  - Norwegian doxazosin post-marketing surveillance study
  - Systolic Hypertension in the Elderly Program (SHEP)
  - Medical Therapy of Prostate Symptoms (MTOPS)
  - Literature Review
- Post-marketing Adverse Events
- Conclusions

Overall Conclusions

- Based on totality of data, doxazosin has a neutral effect on CHF compared to the known beneficial effect of diuretics.
- Pfizer's review of doxazosin data from clinical trials, published literature, and post-marketing adverse events demonstrates that there is no signal regarding a causal relationship between doxazosin and CHF or heart failure-like events

/s/

Zelda McDonald
3/20/01 03:48:41 PM
CSO
Dr. Lipicky signed off on these minutes on 3/20/01