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 2/28/01 Telecon
Date:	3/6/01
Pages including this sheet:	3

From: **Zelda McDonald**
Phone: **301-594-5333**
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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-0110

MT2

Teleconference Minutes

Telecon Date:	February 28, 2001
Date Requested:	Our request: February 27, 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
Norman Stockbridge, M.D., Ph.D.	Team Leader, HFD-110
Zelda McDonald	RHPM, HFD-110

Pfizer

Suzanne LoGalbo, J.D.	Director, Team leader, 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). An initial publication based on interim analysis of the ALLHAT trial has 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. Dr. Lipicky requested this telecon to discuss the Pfizer's role in an Advisory Committee meeting scheduled for May 24, 2001.

Telecon:
Dr. Lipicky stated he is planning a discussion of the published results of ALLHAT at the May 24, 2001 Advisory Committee meeting. The Advisory Committee will be asked what the FDA should do in light of the published results. He invited Pfizer to make a presentation as part of the meeting, but asked that the presentation be no more than 20 minutes long.

Dr. Lipcky emphasized that all fully releasable written material to be sent to the Advisory Committee members would need to be sent to the CDER Advisors and Consultants staff 22 business days prior to the Advisory Committee meeting. The draft Guidance for Industry regarding disclosing information provided to Advisory Committees is available on the FDA Website (http://www.fda.gov/cder/guidance/index.htm) under Procedural Draft.

The questions for the Advisory Committee are drafted early (2 to 4 weeks prior to the meeting), but the final version is not usually available until the day before the meeting. The drafts will be sent to Pfizer for any comments and/or suggestions.

Pfizer stated that they would need to discuss the matter internally before committing to making a presentation.

Dr. Lipicky said that Pfizer's contact at the FDA would be Ms. McDonald

Signature minutes preparer: _____

Concurrence, Chair: _____

Drafted: 3/2/01 Finaled: 3/6/01
RD:
Throckmorton 3/5/01
Stockbridge 3/6/01

/s/

Zelda McDonald
3/6/01 10:41:56 AM
CSO
Dr. Lipicky signed-off on these minutes on 3/6/01