DIVISION OF CARDIO-RENAL DRUG PRODUCTS
FOOD AND DRUG ADMINISTRATION

US Mail address:
FDA/CDER/HFD-110
5600 Fishers Lane
Rockville, MD 20857

Woodmont II
1451 Rockville Pike
Rockville, MD 20852

Transmitted to FAX Number:	212-868-1229
Attention:	**Mr. Salvatore Graziano**
Company Name:	
Phone:	212-594-5300
Subject:	4/4/01 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!

01P-0010

MT4

Minutes of Telecon Meeting
Citizen Petition- ALLHAT Advisory Committee

Date of Meeting: April 4, 2001

IND Number: [ ]

Meeting Chair: Raymond Lipicky, M.D.

Meeting Participants:

FDA, HFD-110

Raymond Lipicky, M.D.	Director, Division 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

Citizen Petitioners

Salvatore Graziano	Attorney, Citizen Petition
Ted Parr	Attorney, Citizen Petition

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 bringing this issue before the Cardio-Renal Advisory Committee. The attorneys representing the Citizen Petition requested this telecon to discuss their presentation for the Advisory Committee meeting scheduled for May 24, 2001.

Meeting

Dr. Lipicky opened the discussion by asking if the Citizen Petitioners had any questions regarding the Advisory Committee meeting scheduled for May 24 and 25, 2001. The petitioners are planning a 20-minute presentation. They will introduce themselves and their position and allocate the majority of the time to Dr. Krakoff, an expert in the field, for their presentation. Dr. Krakoff expects most of the allotted time will be given to answering questions from the committee.

The petitioners asked if the Agency had invited anyone from the ALLHAT study to participate in the discussion. Dr. Lipicky stated that the National Heart, Lung, and Blood Institute would be given 20 minutes to discuss the study and defend their decision to stop the doxazosin arm of the study.

The petitioners stated that Dr. Marvin Konstam, a previous investigator in the ALLHAT study, had offered to assist them but he may be called to testify as an ad hoc member of the Advisory Committee, so they have discontinued communication with him to avoid a conflict of interest. Dr Lipicky stated that the conflict of interest is a real problem and the Advisors and Consultants Staff will have to make a ruling on this issue before the Division knows who will have a conflict of interest.

The petitioners asked if waivers for financial interest should not be granted for this committee since the case is in litigation. The petitioners can pursue this if they believe it is in their best interest, but there may not be an

Advisory Committee meeting in that case. In addition, the Division has declared the only competing product is Hytrin (terazosin hydrochloride) manufactured by Abbott. However, the Advisors and Consultants Staff may not agree with this decision. Frequently, the conflict of interest decisions are not determined until 2-3 days before the meeting.

The petitioners stated they reviewed the Agency's Adverse Reaction database and were stunned regarding the number of reports on doxazosin. The Division has not systematically reviewed these data. However, Pfizer has reviewed the adverse drug reactions and all placebo controlled studies related to heart failure and will be providing these data in their briefing document. In addition, they may summarize what is known about the effect of diuretics on heart failure and support the position that diuretics are good for heart failure and would expect to see less heart failure in patients on diuretics.

The Division has not had an opportunity to validate and confirm the ALLHAT findings, as we have not yet seen the ALLHAT data. Therefore, the Division has not taken definitive action or initiated changes in the labeling. The petitioners stated that the FDA has given reports to the courts that they are looking at the data. Dr. Lipicky stated he was not aware of this and stated that the Division has not seen the data. In addition, the Advisory Committee will be asked if action should be taken.

Conclusion

The petitioners concluded by stating they will continue preparing for the Advisory Committee meeting over the next 2 weeks. Dr. Lipicky stated he wanted to maintain open communication and asked them to call if they have questions.

Meeting Recorder: _____

Concurrence, Chair: _____

cc:
HFD-110/Mathews
Throckmorton, HFD-110
Hirsch, HFD-580
Shames, HFD-580
Colangelo, HFD-580
Draft: 04/13/01
LoCicero 04/16/01
Morgenstern 04/16/01
Final: 04/16/01

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 10:39:21 AM
CSO
Dr. Lipicky signed these minutes on 4/4/01