Endocrinologic and Metabolic Drugs Advisory Committee #73

Food and Drug Administration
Center for Drug Evaluation and Research

Bethesda Marriott, 5151 Pook's Hill Road, Bethesda MD

April 23, 1999

NDA 21-073, Actos (pioglitazone) Takeda Pharmaceuticals

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Agenda (4/15 draft)

8:00 Call to Order, Introductions, Opening Comments:
Henry G. Bone III, M.D., Chair
Endocrinologic and Metabolic Drugs Advisory Committee
Meeting Statement: Kathleen Reedy, Executive Secretary
Endocrinologic and Metabolic Drugs Advisory Committee
Introduction: Solomon Sobel, M.D., Division Director

8:30 Takeda Presentation

9:45 FDA Presentation
Robert Misbin, M.D., Medical Officer, Safety Review

10:15 Break

10:30 Open Public Hearing
Larry Sasich, Pharm.D., Public Citizens Health Research Group
Margaret Himelfarb, Baltimore
Carl Deabate, M.D., New Orleans
Sherwin Schwartz, M.D., San Antonio

11:00 Discussion and Questions

1:00 Lunch

2:00 Discussion of labeling and patient monitoring issues applicable to all products for the treatment of diabetes in this class.

3:30 Adjourn

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Questions
(4/15 draft, subject to edit and change)

1. What comments do you have from the safety standpoint about the effects of pioglitazone on:
   a) liver?

   b) lipids?

   c) hemoglobin?

   d) heart?

2. Do you have any recommendations relating to safety for the labeling of pioglitazone other than for possible effects on the liver?

Class Labeling Questions

1. Should the labeling for other member of the thiazolidinedione class of drugs address the subject of hepatotoxicity observed with troglitazone and, if so, how?

2. Should the labeling for other members of the class specify that liver testing should be performed at periodic intervals and, if so, how frequently?