Food and Drug Administration
Center for Drug Evaluation and Research

SUMMARY MINUTES OF THE
PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE

December 13, 2006

Members Present (Voting)
Daniel S. Pine M.D. *(Acting Chair)*
Jorge Armenteros, M.D.
Jean Bronstein, R.N., M.S.
Andrew Leon, Ph.D.
Delbert Robinson, M.D.

Consultants to the Psychopharmacologic Drugs Advisory Committee (Voting)
Wayne Goodman, M.D.
Susan K. Schultz, M.D.
Gail W. Griffith *(Patient Representative)*
Marcia J. Slattery, M.D., M.H.S.

Psychopharmacologic Drugs Advisory Committee Industry Representative (Non-voting)
Bruce Pollock, M.D., Ph.D.
Dilip Mehta, M.D., Ph.D.

FDA Participants
Robert Temple, M.D.
Thomas Laughren, M.D.
Lisa Jones, M.D., M.P.H.
Mark Levenson, M.D.
Marc Stone, M.D.

Executive Secretary
Cicely Reese, Pharm.D.

Members Not Present
Philip Wang, M.D., Dr. P.H.
Barbara Wells, Pharm.D.

These summary minutes for the December 13, 2006 meeting of the Psychopharmacologic Drugs Advisory Committee were approved on January 17, 2007.

I certify that I attended the December 13, 2006 meeting of the Psychopharmacologic Drugs Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Cicely Reese, Pharm.D.
Designated Federal Official

____/s/_____
Daniel S. Pine, M.D.
Acting Chair

Summary Minutes
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Psychopharmacologic Drugs Advisory Committee

December 13, 2006

The following is an internal report which has not been reviewed. A *verbatim* transcript will be available in approximately two weeks, sent to the Division and posted on the FDA website at:

http://www.fda.gov/ohrms/dockets/ac/cder06.html#PsychopharmacologicDrugs

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

Prior to the meeting, the members and the invited consultants had been provided the background material from the FDA and written statements submitted by the public. The meeting was called to order by Daniel S. Pine, M.D. (Acting Committee Chair); the conflict of interest statement was read into the record by Cicely Reese, Pharm.D. (Designated Federal Officer). There were approximately 430 in attendance.

Attendance:
Psychopharmacologic Drugs Advisory Committee Members Present (voting):
Daniel Pine, M.D. (Acting Chair), Jorge Armenteros, M.D., Jean Bronstein, R.N. M.S. (Consumer Representative), Andrew Leon, Ph.D., and Delbert Robinson, M.D.

Psychopharmacologic Drugs Advisory Committee Members (non-voting):
Dilip Mehta, M.D., Ph.D. (non-voting Industry Representative)
Bruce Pollock, M.D.

Psychopharmacologic Drugs Advisory Committee Consultants (voting):
Wayne Goodman, M.D., Susan Schultz, M.D., and Marcia Slattery, M.D., M.H.S.

Psychopharmacologic Drugs Advisory Committee Patient Representative (voting):
Gail Griffith, M.A.

FDA Participants at the Table:
Robert Temple, M.D., Thomas Laughren, M.D., M. Lisa Jones, M.D., Marc Stone, M.D., Mark Levinson, M.D

Topic:
The committee discussed findings from FDA's meta-analysis on antidepressants and suicidality in adult patients and commented both on the findings and on FDA's general plans for labeling changes to reflect the new information.

Agenda Proceedings

Opening Remarks	Daniel S. Pine, M.D. Acting Chair, Psychopharmacologic Drugs Advisory Committee
. FDA Introductory Remarks & Overview of Issues	Thomas P. Laughren, M.D. Director, Division of Psychiatry Products, CDER, FDA
Antidepressants and Suicidality in Adults: Data Overview	Lisa Jones, M.D., M.P.H Medical Reviewer, Division of Psychiatry Products CDER, FDA
Antidepressants and Suicidality in Adults: Statistical Safety Reviewer Evaluation	Mark Levenson, Ph.D. Statistical Safety Reviewer Division of Biometrics 6
. Antidepressants and Suicidality in Adults: Medical Reviewer Evaluation	Marc Stone, M.D. Senior Medical Reviewer Division of Psychiatry Products
Summary and Issues for Committee	Thomas P. Laughren, M.D. Director, Division of Psychiatry Products, CDER, FDA

Open Public Hearing:

Porto, Kim
Coffin, Chris
Hanson, Ellen
Totten, Julie
Gonzalez, Suzanne
Mann, John
Jones, Allen
Korzie, Nick
Kratochvil, Christopher
Reiger, Darrel
Dolan, Moira
Gruder, Deborrah J.
Olsen, Gwen
Hatcher, Beverly
Liversidge, Ellen
Van Syckel, Lisa
Carpenter, Charles
Clayton, Paula
Dorlester, Diane
Kopolow, Lewis
Glenmullen, Joseph
Reidenberg, Dan
Menzies, Karen/Debra Tucker
Moore, Michele
Noll, Tony
Dick, Mary Margaret
Barnes, Donna
Witczak, Kim
Weiner, Joseph
Heck, Angela
Matthews, Sheila
Carolla, Robert
Watson, Toby Tyler
Crowley, Erin
Vickery, Andy
Hayes, John R
Bryan, Heidi
Farber, Donald J.
Healy, David
Spiller, Lee
Robinowitz, Carolyn
Walton, Sheri
Richner, Jayne
Sharby, Nancy
Sharav, Vera
Moxon, Kendrick
Shern, David
Malmon, Alison
Tracy, Ann Blake
Caine, Eric
Dorsett, Rosemary
Winter, Mary Ellen
Stotland, Nada
Peele, Roger
Swan, Eric
Routhier, Allan
Sheffield, Anne
Yorke, Laurie
Stotland, Hanna
Reynolds III, Charles
Gibbons, Robert
Braslow, Derek
Salzman, Carl
Valuck, Robert
Daviss, Steven

Committee Questions for FDA and Committee Discussion

Charge to the Committee

Please discuss the findings from FDA's meta-analysis on antidepressants and suicidality in adult patients and comment both on the findings and on our general plans for labeling changes to reflect this new information. We would also encourage you to discuss possible research strategies to better understand the apparent risk of suicidality with antidepressant use in younger patients.

Committee Discussion

The committee suggested the data presented by the FDA lead to reasonable conclusions and the finding of increased short-term risk for suicidality with antidepressant treatment in pediatric patients does appear to extend into the younger adults. The committee also suggested that FDA data show that beyond age 30, antidepressants begin to show an expected protective effect for suicidality, which is most pronounced beyond age 65. The committee was clear to note that age is a possible proxy to a different causation which the FDA needs to further investigate.

Research strategies suggested by the committee to help FDA better understand the apparent risk of suicidality with antidepressant use in younger patients include exploring creative ways to communicate the issue of suicidality and treatment of depression to the public. The use of health education experts to design ways to disseminate the information was also suggested. The committee was strong in its agreement that the FDA should increase transparency in its data presentation to avoid possible negative consequences.

From the discussion, the committee agreed that there was a need to establish two questions in making further recommendations to the FDA. There was an intermediate vote after Question 1, when the Committee voted unanimously to hold a vote on the Question “Should the suggested label change be extended into the black box?”

(see transcript for additional details)

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Additional questions to the committee

1. **Does the committee feel that there is need to alter the current labeling of antidepressant drugs to include extention to young adult age?**

Yes - 8 No - 0

2. **Should the suggested label change be extended into the black box?**

Yes - 6 No - 2

Those voting yes for question (2) did so with the caveat to include information about risk of suicidality and untreated depression.

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The Meeting adjourned for the day at approximately 5:35 p.m.