



August 20, 2004

Dear Psychopharmacologic Drugs Advisory Committee Members/Consultants
and Pediatric Advisory Committee Members/Consultants:

With this letter, I am forwarding to you an Addendum (dated August 20, 2004) to the FDA briefing package you recently received in preparation for September 13-14, 2004, joint Advisory Committee meeting.

As you will see, this package contains four (4) separate documents as follows:

- Tab 1: Product Labeling for Prozac® (fluoxetine hydrochloride);
- Tab 2: Product Labeling for Zoloft® (sertraline hydrochloride) Tablets and Oral Concentrate;
- Tab 3: FDA Talk Paper – dated August 20, 2004; and,
- Tab 4: Draft Agenda for the September 13 and 14, 2004 Advisory Committee meeting.

As a reminder, the meeting will take place on **Monday, September 13, 2004, and Tuesday, September 14, 2004**. On Monday, we are scheduled to begin the discussions at 8:00 a.m. and adjourn at 6:30 p.m. On Tuesday, the meeting will begin at 8 a.m. and adjourn at 5 p.m. The meeting will take place at the **Holiday Inn**, in Bethesda, Maryland located at 8120 Wisconsin Avenue (telephone number: 301-652-2000).

And finally, by now all your travel arrangements, both transportation and hotel, should be confirmed. If by chance you have not received confirmation of your travel itinerary either via fax or email, please contact Ms. La' Nise Giles of our office immediately at: (301) 827-6791. She will assist you.

Please feel free to contact me with any questions or issues regarding the meeting. I can be reached at: (301) 827-6790 or PatelA@cder.fda.gov.

I look forward to meeting you in September and to some very interesting discussions.

Sincerely,

Anuja M. Patel, M.P.H
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Enclosure