



2202 N. West Shore Blvd., Suite 450
Tampa, Florida 33607
(813) 288-0040

October 3, 2005

Karen M. Templeton-Somers, Ph.D.
Supervisory Health Science Administrator
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Executive Programs
Advisors and Consultants Staff
5600 Fishers Lane (Bldg 5630, Rm. 1091)
Rockville, MD 20857-0001

RE: LETTER OF ERRATA
NDA 21,336/21,708
BACKGROUND DOCUMENT :
October 26, 2005 Meeting of the Psychopharmacologic
Drug Advisory Committee Meeting

Dear Dr. Templeton-Somers:

As discussed, Somerset Pharmaceuticals, Inc. has identified a typographical error in the Executive Summary, page 6, of the September 26, 2005 Back Ground Document for NDA 21,366/21,708, EMSAM[®], indicated for the treatment of Major Depressive Disorder.

Identification and correction of this error is as follows:

Page 6, 1st bullet point should read:

- (Parnate[®] 30 mg/day, a MAOI approved **with** dietary modifications and indicated for MDD).

Please provide this correction, as part of Back Ground Package, to the Advisory Committee as well as part of the Freedom of Information posting.

Sincerely,

A handwritten signature in black ink that reads "Melissa L. Goodhead". The signature is written in a cursive style with a large, prominent "M" and "G".

Melissa L. Goodhead, B.Sc., RAC
Group Director, Regulatory Affairs/Quality Assurance

:mlg