



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

September 28, 2005

**FILE COPY**

William W. Vodra  
Arnold & Porter LLP  
555 Twelfth Street, NW  
Washington, DC 20004-1202

Dear Mr. Vodra:

Your petition on behalf of Ross J. Baldessarini, M.D. and Frederick K. Goodwin, M.D., requesting the Food and Drug Administration to amend or permit amendment of the labeling of all lithium-containing drugs to include additional indication "to reduce the incidence of suicide and suicide attempts in manic-depressive illness" was received by this office on 09/28/2005. It was assigned docket number 2005P-0402/CP 1 and it was filed on 09/28/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

cc: Ross J. Baldessarini, M.D.  
Mailman Research Center 306  
McLean Hospital, 115 Mill Street  
Belmont, MA 02478-9106

2005P-0402

ACK 1