



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 21, 2005

FILE COPY

John B. Dubeck
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, DC 20001

Dear Mr. Dubeck:

Your petition requesting the Food and Drug Administration to require that generic version of Wellbutrin XL (bupropion hydrochloride extended-release tablets) meet specific criteria in order to be considered bioequivalent to Wellbutrin XL was received by this office on 12/20/2005. It was assigned docket number 2005P-0498/CP 1 and it was filed on 12/20/2005. 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

2005P-0498

ACK 1