DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 15, 2013

Michael Kukulka
Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015

Dear Mr. Kukulka:

Your petition to the Food and Drug Administration requesting FDA to refrain from approving any Abbreviated New Drug Application (ANDA) referencing DEXILANT (dexlansoprazole) delayed-release capsules for oral use, unless the conditions specified in the petition are satisfied, was received by this office on 2/15/2013. It was assigned docket number FDA-2013-P-0198/CP1, and it was filed on 2/15/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)