



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 15, 2013

FILE COPY

David L. Rosen, BS Pharm., JD
Foley & Lardner LLP
Attorneys at Law
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143

Dear Dr. Rosen:

Your petition to the Food and Drug Administration requesting FDA to amend the 2011 Guidance for Nilutamide, was received by this office on 3/15/2013. It was assigned docket number FDA-2013-P-0335/CP1, and it was filed on 03/15/2013. 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,

A handwritten signature in black ink, reading "Gloria Ortega", is positioned above the printed name.

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