DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 5, 2014

FILE COPY

Sidney Wolfe, M.D.
Founder, Senior Adviser
Public Citizen's Health Research Group
1600 20th Street N.W.
Washington, D.C. 20009

Dear Dr. Wolfe:

Your petition to the Food and Drug Administration requesting the Agency to add a black box warning about the increased risks of heart attacks and other cardiovascular dangers to the product labels of all testosterone-containing drugs presently on the market in the U.S., was received by this office on 2/25/2014. It was assigned docket number FDA-2014-P-0258/CP1, and it was filed on 3/5/2014. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)