DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JAN 16 2013

Michael A. Carome, M.D., Deputy Director
Sidney M. Wolfe, M.D., Director
Public Citizen Health Research Group
1600 20th St., N.W.
Washington, D.C. 20009

Dear Drs. Carome and Wolfe,

Thank you for your letter of December 21, 2012 to me and Dr. John Farley, in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). You reference the Anti-Infective Drugs Advisory Committee (AIDAC) meeting held on November 28, 2012, and express your objection to approval of bedaquiline (Sirturo™) as part of a combination-drug regimen for treatment of multi-drug resistant tuberculosis.

We have carefully considered the issues you raise in your letter as well as the advice from the AIDAC in reaching our decision on approval. The complete Approval Package for bedaquiline (Sirturo™), including clinical and pharmacologic reviews as well as decisional memos, will be publicly available online at Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm) within six to eight weeks.

In addition, please note that the labeling, approval letter, and Medication Guide for bedaquiline (Sirturo™) are currently posted at:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist

Thank you for contacting us regarding this matter and sharing your views. If we can answer any further questions, please do not hesitate to contact us.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research