U.S. FOOD & DRUG ADMINISTRATION

OCT 1 1 2019

Meena Aladdin, M.S., Ph.D
Michael A. Carmone, M.D.
Sidney M. Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Re: Docket No. FDA-2019-P-1818

Dear Dr. Aladdin, Dr. Carmone, and Dr. Wolfe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 16, 2019. Your petition requests that FDA take action regarding the product labeling and risk evaluation and mitigation strategy (REMS) for the osteoporosis drug Prolia (denosumab). Specifically, you request the addition of a boxed warning to the product labeling and an updated REMS to address the risk of multiple vertebral fractures following discontinuation of Prolia treatment.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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