



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 3 2013

Steven A. Zecola
exemption 6

Re: Docket No. FDA-2013-P-0695

Dear Mr. Zecola:

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 June 6, 2013. Your petition requests that the Agency undertake an internal examination of its practices, regulations and organizational structure for addressing metastatic cancer, and to modify those items as recommended in the petition.

FDA has been unable to reach a decision on your petition because it raises significant 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 possible given the numerous demands on the Agency's resources.

Sincerely,

for

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research